US007899511C1

(12) EX PARTE REEXAMINATION CERTIFICATE (8735th)

United States Patent
Shults et al.

(10) Number: US 7,899,511 C1
(45) Certificate Issued: *Dec. 6, 2011

(54) **LOW OXYGEN IN VIVO ANALYTE SENSOR**

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Reexamination Request:
No. 90/011,610, Mar. 31, 2011

Reexamination Certificate for:

Patent No.:	**7,899,511**
Issued:	**Mar. 1, 2011**
Appl. No.:	**11/333,837**
Filed:	**Jan. 17, 2006**

(*) Notice: This patent is subject to a terminal disclaimer.

Related U.S. Application Data

(63) Continuation-in-part of application No. 11/077,714, filed on Mar. 10, 2005, now Pat. No. 7,885,697.
(60) Provisional application No. 60/614,764, filed on Sep. 30, 2004, provisional application No. 60/614,683, filed on Sep. 30, 2004, provisional application No. 60/587,800, filed on Jul. 13, 2004, and provisional application No. 60/587,787, filed on Jul. 13, 2004.

(51) **Int. Cl.**
A61B 5/05 (2006.01)
A61B 5/00 (2006.01)

(52) **U.S. Cl.** **600/347**; 600/365; 600/345
(58) **Field of Classification Search** 600/347
See application file for complete search history.

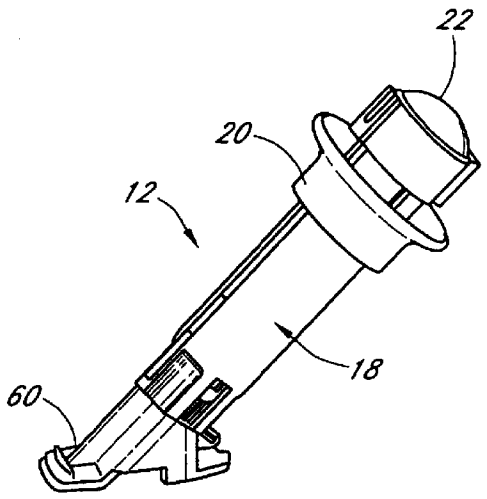
(56) **References Cited**

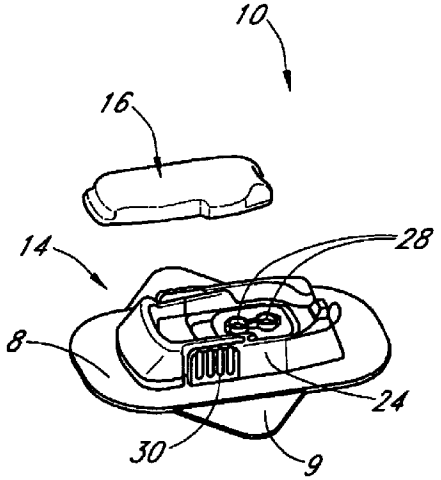
To view the complete listing of prior art documents cited during the proceeding for Reexamination Control Number 90/011,610, please refer to the USPTO's public Patent Application Information Retrieval (PAIR) system under the Display References tab.

Primary Examiner—Beverly M. Flanagan

(57) **ABSTRACT**

The present invention relates generally to systems and methods for measuring an analyte in a host. More particularly, the present invention relates to systems and methods for transcutaneous and subcutaneous measurement of glucose in a host.





EX PARTE REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

Claims **1-4**, **6-14** and **16-28** are determined to be patentable as amended.

Claims **5**, **15** and **29-41**, dependent on an amended claim, are determined to be patentable.

New claims **42** and **43** are added and determined to be patentable.

1. A *transcutaneous* glucose sensor system comprising:
an in vivo portion and an ex vivo portion;
wherein the in vivo portion comprises:
an electrode configured to measure a concentration of glucose in a host, wherein the electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2;
a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and
wherein the ex vivo portion comprises sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode, wherein the sensor electronics are configured to measure the current flow in at least a pico-Amp range; wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL, and wherein the system is configured to measure the current flow associated with the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L.

2. The glucose sensor system of **[**claim **1]***claims 1 or 42*, wherein the sensor electronics are configured to directly measure the current flow associated with the electrode.

3. The glucose sensor system of **[**claim **1]***claims 1 or 42*, further comprising an analog-to-digital converter configured to translate the current flow measurement to a digital signal.

4. The glucose sensor system of **[**claim **1]***claims 1 or 42*, wherein the membrane comprises a resistance domain configured with a permeability ratio of at least about 50:1 co-analyte to glucose concentration.

6. The glucose sensor system of **[**claim **1]***claims 1 or 42*, wherein the membrane comprises an enzyme.

7. The glucose sensor system of **[**claim **1]***claims 1 or 42*, wherein the system is configured to determine a concentration of the glucose in a biological sample via measurement of hydrogen peroxide produced by an enzyme-catalyzed reaction of glucose with oxygen.

8. The glucose sensor system of **[**claim **1]***claims 1 or 42*, wherein the system is configured to have an operable life implanted within a host of at least about one week.

9. The glucose sensor system of **[**claim **1]***claims 1 or 42*, wherein the system is configured to measure glucose with substantial linearity at an oxygen concentration of less than about 0.3mg/L.

10. The glucose sensor system of **[**claim **1]***claims 1 or 42*, wherein the system is configured such that less than about 1μg of enzyme is consumed over 7 day of continuous operation.

11. The glucose sensor system of **[**claim **1]***claims 1 or 42*, wherein the membrane comprises a polyurethane.

12. A *transcutaneous* glucose sensor system comprising:
an in vivo portion and an ex vivo portion;
wherein the in vivo portion comprises:
an electrode configured to measure a concentration of glucose in a host;
a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and
wherein the ex vivo portion comprises sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode;
wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L, and wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL.

13. The glucose sensor system of **[**claim **12]***claims 12 or 43*, wherein the electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2.

14. The glucose sensor system of **[**claim **12]***claims 12 or 43*, wherein the membrane comprises a resistance domain configured with a permeability ratio of at least about 50:1 co-analyte to glucose concentration.

16. The glucose sensor system of **[**claim **12]***claims 12 or 43*, wherein the membrane comprises an enzyme.

17. The glucose sensor system of **[**claim **12]***claims 12 or 43*, wherein the glucose sensitivity is from about 1 pA/mg/dL to about 10 pA/mg/dL.

18. The glucose sensor system of **[**claim **12]***claims 12 or 43*, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.15 mg/L.

19. The glucose sensor system of **[**claim **12]***claims 12 or 43*, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.05 mg/L.

20. The glucose sensor system of **[**claim **12]***claims 12 or 43*, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.02 mg/L.

21. The glucose sensor system of **[**claim **12]***claims 12 or 43*, wherein the sensor electronics are configured to directly measure the current flow associated with the electrode.

22. The glucose sensor system of **[**claim **12]***claims 12 or 43*, further comprising an analog-to-digital converter configured to translate the current flow measurement to a digital signal.

23. The glucose sensor system of **[**claim **12]***claims 12 or 43*, wherein the system is configured to determine a concentration of glucose in a biological sample via measurement of hydrogen peroxide produced by an enzyme-catalyzed reaction of glucose with oxygen.

24. The glucose sensor system of **[**claim **12]***claims 12 or 43*, wherein the system is configured to have an operable life implanted within a host of at least about one week.

25. The glucose sensor system of **[**claim **12]***claims 12 or 43*, wherein the system is configured to measure glucose with substantial linearity at an oxygen concentration of less than about 0.3mg/L.

26. The glucose sensor system of **[**claim **12]***claims 12 or 43*, wherein the system is configured such that less than about 1μg of enzyme is consumed over 7 days of continuous operation.

27. The glucose sensor system of **[**claim **12]***claims 12 or 43*, wherein the membrane comprises a polyurethane.

28. A glucose sensor system comprising:

an electrode configured to measure a concentration of glucose in a host;

a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and

sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode;

wherein the system is configured to use oxygen from a biological fluid surrounding the membrane to catalyze a reaction of glucose and oxygen, wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL, and wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L.

42. A glucose sensor system comprising:

an electrode configured to measure a concentration of glucose in a host, wherein the electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2;

a membrane disposed over the electrode and configured to limit transport of glucose to the electrode via a substantially uniform transport of glucose across the membrane; and

sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode, wherein the sensor electronics are configured to measure the current flow in at least a picoAmp range; wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL, and wherein the system is configured to measure the current flow associated with the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L.

43. A glucose sensor system comprising:

an electrode configured to measure a concentration of glucose in a host;

a membrane disposed over the electrode and configured to limit transport of glucose to the electrode via a substantially uniform transport across the membrane; and

sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode;

wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L; and wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL.

* * * * *

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/011,610	03/31/2011	7899511	DEXCOM.063X2	5743

68851 7590 10/04/2011

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EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 10/04/2011

Please find below and/or attached an Office communication concerning this application or proceeding.

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EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. *90/011,610*.

PATENT NO. *7899511*.

ART UNIT *3993*.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Notice of Intent to Issue Ex Parte Reexamination Certificate	Control No.	Patent Under Reexamination
	90/011,610	7899511
	Examiner	Art Unit
	BEVERLY FLANAGAN	3993

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

1. ☒ Prosecution on the merits is (or remains) closed in this *ex parte* reexamination proceeding. This proceeding is subject to reopening at the initiative of the Office or upon petition. *Cf.* 37 CFR 1.313(a). A Certificate will be issued in view of
   - (a) ☒ Patent owner's communication(s) filed: *25 August 2011*.
   - (b) ☐ Patent owner's late response filed: _____.
   - (c) ☐ Patent owner's failure to file an appropriate response to the Office action mailed: _____.
   - (d) ☐ Patent owner's failure to timely file an Appeal Brief (37 CFR 41.31).
   - (e) ☐ Other: _____.

   Status of *Ex Parte* Reexamination:
   - (f) Change in the Specification: ☐ Yes ☒ No
   - (g) Change in the Drawing(s): ☐ Yes ☒ No
   - (h) Status of the Claim(s):
     - (1) Patent claim(s) confirmed: _____.
     - (2) Patent claim(s) amended (including dependent on amended claim(s)): *1-41*
     - (3) Patent claim(s) canceled: _____.
     - (4) Newly presented claim(s) patentable: 42 and 43.
     - (5) Newly presented canceled claims: _____.
     - (6) Patent claim(s) ☐ previously ☐ currently disclaimed: _____
     - (7) Patent claim(s) not subject to reexamination: _____.

2. ☒ Note the attached statement of reasons for patentability and/or confirmation. Any comments considered necessary by patent owner regarding reasons for patentability and/or confirmation must be submitted promptly to avoid processing delays. Such submission(s) should be labeled: "Comments On Statement of Reasons for Patentability and/or Confirmation."
3. ☐ Note attached NOTICE OF REFERENCES CITED (PTO-892).
4. ☐ Note attached LIST OF REFERENCES CITED (PTO/SB/08 or PTO/SB/08 substitute).
5. ☐ The drawing correction request filed on _____ is: ☐ approved ☐ disapproved.
6. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
   a)☐ All b)☐ Some* c)☐ None of the certified copies have
   - ☐ been received.
   - ☐ not been received.
   - ☐ been filed in Application No. _____.
   - ☐ been filed in reexamination Control No. _____.
   - ☐ been received by the International Bureau in PCT Application No. _____.

   * Certified copies not received: _____.
7. ☐ Note attached Examiner's Amendment.
8. ☐ Note attached Interview Summary (PTO-474).
9. ☐ Other: _____.

cc: Requester (if third party requester)

Claims Patentable

Claims 1-41 are patentable as amended. Newly filed claims 42 and 43 are patentable.

STATEMENT OF REASONS FOR PATENTABILITY AND/OR CONFIRMATION

The following is an examiner's statement of reasons for patentability and/or confirmation of the claims found patentable in this reexamination proceeding: The prior art does not teach or fairly address the invention as recited in independent claims 1, 12, 28, 42 and 43 and 17 of U.S. Patent No. 7,899,511. Specifically, the prior art references of Kusano and Rhodes do not teach the limitations of "in vivo and ex vivo portions" (added to claims 1 and 12 by amendments) and "a substantially uniform transport of glucose across the membrane" (in newly filed claims 42 and 43). Regarding claim 28, the amendment adding the limitation of "wherein the system is configured to use oxygen from a biological fluid surrounding the membrane to catalyze a reaction of glucose and oxygen" is not taught by the combination of Kerner in view of Kusano. The examiner agrees that modifying the device of Kerner to include the "snorkel" or Kusano would mean that the oxygen used with such a combination would be from external air intake and not from the biological fluid surrounding the membrane. Accordingly, claims 1-43 are patentable.

Any comments considered necessary by PATENT OWNER regarding the above statement must be submitted promptly to avoid processing delays. Such submission by the patent owner should be labeled: "Comments on Statement of Reasons for Patentability and/or Confirmation" and will be placed in the reexamination file.

Conclusion

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Any inquiry concerning this communication or earlier communications from the Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Signed:

/Beverly M. Flanagan/

Beverly M. Flanagan
CRU Examiner
GAU 3993
(571) 272-4766

Conferee /JRJ/

Conferee 

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent	:	US 7,899,511
Reexam. No	:	90/011,610
Filed	:	3/31/2011
For	:	LOW OXYGEN IN VIVO ANALYTE SENSOR
Examiner	:	Flanagan, Beverly M.
Art Unit	:	3993
Conf No.	:	5743

SUPPLEMENTAL AMENDMENT

Mail Stop *Ex Parte* Reexam
Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action dated June 23, 2011 ("Office Action"), and supplemental to the response dated August 23, 2011, the Patent Owner herewith respectfully requests entry of the following amendment and reconsideration and allowance of the pending claims in light of the remarks presented herein.

AMENDMENT TO THE CLAIMS

1. (Amended) A transcutaneous glucose sensor system comprising:

an *in vivo* portion and an *ex vivo* portion;

wherein the *in vivo* portion comprises:

an electrode configured to measure a concentration of glucose in a host, wherein the electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2;

a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and

wherein the *ex vivo* portion comprises sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode, wherein the sensor electronics are configured to measure the current flow in at least a picoAmp range; wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL, and wherein the system is configured to measure the current flow associated with the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L.

2. (Amended) The glucose sensor system of [claim 1] claims 1 or 42, wherein the sensor electronics are configured to directly measure the current flow associated with the electrode.

3. (Amended) The glucose sensor system of [claim 1] claims 1 or 42, further comprising an analog-to-digital converter configured to translate the current flow measurement to a digital signal.

4. (Amended) The glucose sensor system of [claim 1] claims 1 or 42, wherein the membrane comprises a resistance domain configured with a permeability ratio of at least about 50:1 co-analyte to glucose concentration.

5. (Original) The glucose sensor system of claim 4, wherein the permeability ratio is at least about 200:1.

6. (Amended) The glucose sensor system of [claim 1] claims 1 or 42, wherein the membrane comprises an enzyme.

7. (Amended) The glucose sensor system of [claim 1] claims 1 or 42, wherein the system is configured to determine a concentration of the glucose in a biological sample via measurement of hydrogen peroxide produced by an enzyme-catalyzed reaction of glucose with oxygen.

8. (Amended) The glucose sensor system of [claim 1] claims 1 or 42, wherein the system is configured to have an operable life implanted within a host of at least about one week.

9. (Amended) The glucose sensor system of [claim 1] claims 1 or 42, wherein the system is configured to measure glucose with substantial linearity at an oxygen concentration of less than about 0.3mg/L.

10. (Amended) The glucose sensor system of [claim 1] claims 1 or 42, wherein the system is configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation.

11. (Amended) The glucose sensor system of [claim 1] claims 1 or 42, wherein the membrane comprises a polyurethane.

12. (Amended) A transcutaneous glucose sensor system comprising:

an *in vivo* portion and an *ex vivo* portion;

wherein the *in vivo* portion comprises:

an electrode configured to measure a concentration of glucose in a host;

a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and

wherein the *ex vivo* portion comprises sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode;

wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L; and wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL.

13. (Amended) The glucose sensor system of [claim 12] claims 12 or 43, wherein the electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2.

14. (Amended) The glucose sensor system of [claim 12] claims 12 or 43, wherein the membrane comprises a resistance domain configured with a permeability ratio of at least about 50:1 co-analyte to glucose concentration.

15. (Original) The glucose sensor system of claim 14, wherein the permeability ratio is at least about 200:1.

16. (Amended) The glucose sensor system of [claim 12] claims 12 or 43, wherein the membrane comprises an enzyme.

17. (Amended) The glucose sensor system of [claim 12] claims 12 or 43, wherein the glucose sensitivity is from about 1 pA/mg/dL to about 10 pA/mg/dL.

18. (Amended) The glucose sensor system of [claim 12] claims 12 or 43, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.15 mg/L.

19. (Amended) The glucose sensor system of [claim 12] claims 12 or 43, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.05 mg/L.

20. (Amended) The glucose sensor system of [claim 12] claims 12 or 43, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.02 mg/L.

21. (Amended) The glucose sensor system of [claim 12] claims 12 or 43, wherein the sensor electronics are configured to directly measure the current flow associated with the electrode.

22. (Amended) The glucose sensor system of [claim 12] claims 12 or 43, further comprising an analog-to-digital converter configured to translate the current flow measurement to a digital signal.

23. (Amended) The glucose sensor system of [claim 12] claims 12 or 43, wherein the system is configured to determine a concentration of glucose in a biological sample via measurement of hydrogen peroxide produced by an enzyme-catalyzed reaction of glucose with oxygen.

24. (Amended) The glucose sensor system of [claim 12] claims 12 or 43, wherein the system is configured to have an operable life implanted within a host of at least about one week.

25. (Amended) The glucose sensor system of [claim 12] claims 12 or 43, wherein the system is configured to measure glucose with substantial linearity at an oxygen concentration of less than about 0.3mg/L.

26. (Amended) The glucose sensor system of [claim 12] claims 12 or 43, wherein the system is configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation.

27. (Amended) The glucose sensor system of [claim 12] claims 12 or 43, wherein the membrane comprises a polyurethane.

28. (Amended) A glucose sensor system comprising:

an electrode configured to measure a concentration of glucose in a host;

a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and

sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode;

wherein the system is configured to use oxygen from a biological fluid surrounding the membrane to catalyze a reaction of glucose and oxygen, wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL, and wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L.

29. (Original) The glucose sensor system of claim 28, wherein the electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2.

30. (Original) The glucose sensor system of claim 28, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.15 mg/L.

31. (Original) The glucose sensor system of claim 28, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.05 mg/L.

32. (Original) The glucose sensor system of claim 28, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.02 mg/L.

33. (Original) The glucose sensor system of claim 28, wherein the sensor electronics are configured to directly measure the current flow associated with the electrode.

34. (Original) The glucose sensor system of claim 28, further comprising an analog-to-digital converter configured to translate the current flow measurement to a digital signal.

35. (Original) The glucose sensor system of claim 28, wherein the membrane comprises a resistance domain configured with a permeability ratio of at least about 50:1 co-analyte to glucose concentration.

36. (Original) The glucose sensor system of claim 35, wherein the permeability ratio is at least about 200:1.

37. (Original) The glucose sensor system of claim 28, wherein the membrane comprises an enzyme.

38. (Original) The glucose sensor system of claim 28, wherein the system is configured to determine a concentration of glucose in a biological sample via measurement of hydrogen peroxide produced by an enzyme-catalyzed reaction of glucose with oxygen.

39. (Original) The glucose sensor system of claim 28, wherein the system is configured to have an operable life implanted within a host of at least about one week.

40. (Original) The glucose sensor system of claim 28, wherein the system is configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation.

41. (Original) The glucose sensor system of claim 28, wherein the membrane comprises a polyurethane.

42. (New) A glucose sensor system comprising:

an electrode configured to measure a concentration of glucose in a host, wherein the electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2;

a membrane disposed over the electrode and configured to limit transport of glucose to the electrode via a substantially uniform transport of glucose across the membrane; and

sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode, wherein the sensor electronics are configured to measure the current flow in at least a picoAmp range; wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL, and wherein the system is configured to measure the current flow associated with the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L.

43. (New) A glucose sensor system comprising:

an electrode configured to measure a concentration of glucose in a host;

a membrane disposed over the electrode and configured to limit transport of glucose to the electrode via a substantially uniform transport across the membrane; and

sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode;

wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L; and wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL.

SUMMARY OF INTERVIEW

Attendees, Date and Type of Interview

The personal interview was conducted on July 27, 2011 and attended by Examiners Beverly Flanagan, Jeanne Clark, David Reip, and Andy Kashnikow and the Patent Owner's representatives Laura Johnson, Paul Lee, and Kaare Larson.

Exhibits and/or Demonstrations

N/A.

Identification of Claims Discussed

Claims 1, 12, and 28.

Identification of Art Discussed

U.S. Patent Publication No. 2003/0032874 ("Rhodes") and Kusano, H., Glucose enzyme electrode with percutaneous interface which operates independently of dissolved oxygen, *Clin. Phys. Physiol. Meas.*, vol. 10, 1:1-9 (1989) ("Kusano").

Proposed Amendments, Principal Arguments, Results of Interview, and Other Matters

The Patent Owner's representatives proposed amending Claims 1 and 12 to recite that the glucose sensor system is a transcutaneous system with an *in vivo* portion and an *ex vivo* portion or that the membrane of the system is configured to limit transport of glucose to the electrode via a substantially uniform transport across the membrane. The Examiners agreed that either amendment would overcome the Office Action's anticipatory rejection based on Rhodes. With regard to Claims 1 and 12, the Patent Owner's representatives explained that it would not have been obvious to modify the non-transcutaneous implantable device disclosed in Rhodes to include the air intake hole described in Kusano. With regard to Claim 28, the Patent Owner's representatives proposed amending the claim to clarify that the recited system is configured to use oxygen from a biological fluid surrounding the membrane. The Patent Owner's representatives explained why modifying the Kerner device to include Kusano's air intake would not have arrived at the claimed invention, because the oxygen used with such a device would be from the air intake and not from the biological fluid surrounding the membrane, due to an oxygen concentration

gradient. The Examiners agreed with this explanation and requested that the explanations presented during the interview be included in the formal response.

With regard to the *Ex Parte* Reexamination Interview Summary filed by the Examiner on August 18, 2011, the Patent Owner would respectfully like to correct the Examiner's statement that the "Rhodes' device is not subcutaneous." The Patent Owner believes that the term "subcutaneous" should have been "transcutaneous," as it was agreed upon during the interview that the Rhodes device is not a transcutaneous device.

CLAIM STATUS AND SUPPORT FOR AMENDMENTS (37 CFR 1.530(e))

1. **Pending – Amended.** Amended Claim 1 includes the limitation that the glucose sensor system is a transcutaneous system with an *in vivo* portion and an *ex vivo* portion. Support for this limitation can be found, *e.g.*, at Col. 8, Lns. 7-20 and Col. 15, Lns. 52-57 of the '511 Patent.

2. **Pending – Amended.** Claim 2 has been amended to depend from Claims 1 or 42.

3. **Pending – Amended.** Claim 3 has been amended to depend from Claims 1 or 42.

4. **Pending – Amended.** Claim 4 has been amended to depend from Claims 1 or 42.

5. **Pending – Unchanged.**

6. **Pending – Amended.** Claim 6 has been amended to depend from Claims 1 or 42.

7. **Pending – Amended.** Claim 7 has been amended to depend from Claims 1 or 42.

8. **Pending – Amended.** Claim 8 has been amended to depend from Claims 1 or 42.

9. **Pending – Amended.** Claim 9 has been amended to depend from Claims 1 or 42.

10. **Pending – Amended.** Claim 10 has been amended to depend from Claims 1 or 42.

11. **Pending – Amended.** Claim 11 has been amended to depend from Claims 1 or 42.

12. **Pending – Amended.** Amended Claim 12 includes the limitation that the glucose sensor system is a transcutaneous system with an *in vivo* portion and an *ex vivo* portion. Support for this limitation can be found, *e.g.*, at Col. 8, Lns. 7-20 and Col. 15, Lns. 52-57 of the '511 Patent.

13. **Pending – Amended.** Claim 13 has been amended to depend from Claims 12 or 43.

14. **Pending – Amended.** Claim 14 has been amended to depend from Claims 12 or 43.

15. **Pending – Unchanged.**

16. **Pending – Amended.** Claim 16 has been amended to depend from Claims 12 or 43.

17. **Pending – Amended.** Claim 17 has been amended to depend from Claims 12 or 43.

18. **Pending – Amended.** Claim 18 has been amended to depend from Claims 12 or 43.

19. **Pending – Amended.** Claim 19 has been amended to depend from Claims 12 or 43.

20. **Pending – Amended.** Claim 20 has been amended to depend from Claims 12 or 43.

21. **Pending – Amended.** Claim 21 has been amended to depend from Claims 12 or 43.

22. **Pending – Amended.** Claim 22 has been amended to depend from Claims 12 or 43.

23. **Pending – Amended.** Claim 23 has been amended to depend from Claims 12 or 43.

24. **Pending – Amended.** Claim 24 has been amended to depend from Claims 12 or 43.

25. **Pending – Amended.** Claim 25 has been amended to depend from Claims 12 or 43.

26. **Pending – Amended.** Claim 26 has been amended to depend from Claims 12 or 43.

27. **Pending – Amended.** Claim 27 has been amended to depend from Claims 12 or 43.

28. **Pending – Amended.** Amended Claim 28 includes the limitation that the glucose sensor system is configured to use oxygen from a biological fluid surrounding the membrane to catalyze a reaction of glucose and oxygen. Support for this limitation can be found, *e.g.*, at Col. 7, Lns. 37-44 and Col. 75, Ln. 63 – Col. 76, Ln. 2 of the '511 Patent.

29. **Pending – Unchanged.**

30. **Pending – Unchanged.**

31. **Pending – Unchanged.**

32. **Pending – Unchanged.**

33. **Pending – Unchanged.**

34. **Pending – Unchanged.**

35. **Pending – Unchanged.**

36. **Pending – Unchanged.**

37. **Pending – Unchanged.**

38. **Pending – Unchanged.**

39. **Pending – Unchanged.**

40. **Pending – Unchanged.**

41. **Pending – Unchanged.**

42. **Pending – New.** New Claim 42 includes the limitation that the membrane of the system is configured to limit transport of glucose to the electrode via a substantially uniform transport across the membrane. Support for this limitation can be found, *e.g.*, at Col. 7, Lns. 51-57 and Col. 70, Lns. 1-4 of the '511 Patent.

43. **Pending – New.** New Claim 43 includes the limitation that the membrane of the system is configured to limit transport of glucose to the electrode via a substantially uniform transport across the membrane. Support for this limitation can be found, *e.g.*, at Col. 7, Lns. 51-57 and Col. 70, Lns. 1-4 of the '511 Patent.

REMARKS

Claim Status

Claims 1-41 of the '511 Patent are subject to reexamination. By virtue of this Amendment, Claims 1-4, 6-14, and 16-28 have been amended, and new Claims 42 and 43 have been added. Accordingly, upon entry of this Amendment, Claims 1-43 will be pending and under reexamination.

Prior Art Rejections

A. Claims 1, 2, 4-8, 11-18, 21, 23, 24, 27-30, 33, 35-39, and 41 are patentable over Rhodes.

Claims 1, 2, 4-8, 11-18, 21, 23, 24, 27-30, 33, 35-39, and 41 stand rejected under 35 U.S.C. 102(b) as allegedly anticipated by U.S. Patent Publication No. 2003/0032874 ("Rhodes"). The Patent Owner respectfully traverses this anticipatory rejection. "A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." *See, e.g., In re Paulsen*, 31 U.S.P.Q.2d 1671 (Fed. Cir. 1994).

Claims 1 and 12, from which Claims 2, 4-8, 11, 13-18, 21, 23, 24, and 27 depend, have been amended to recite that the glucose sensor system is a transcutaneous system with an *in vivo* portion and an *ex vivo* portion. Support for this limitation can be found, *e.g.*, at Col. 8, Lns. 7-20 and Col. 15, Lns. 52-57 of the '511 Patent. As acknowledged by the Examiner during the Examiner Interview of July 27, 2011, Rhodes does not teach a glucose sensor system that is a transcutaneous system with an *in vivo* portion and an *ex vivo* portion. See *Ex Parte* Reexamination Interview Summary filed by the Examiner on August 18, 2011 (stating that "Rhodes does not include both an *in vivo* and an *ex vivo* portion"). For at least this reason, the Patent Owner submits that the anticipatory rejection of Claims 1, 2, 4-8, 11-18, 21, 23, 24, and 27 cannot stand. Accordingly, withdrawal of this anticipatory rejection is respectfully requested.

With regard to Claims 28-30, 33, 35-39, and 41, according to the Examiner, "Rhodes also teaches that testing was conducted up to a glucose concentration of 400 mg/dL, with oxygen concentration down to 0/1 mg/dL [sic] (see Example 2, page 10)." Office Action, at page 4. While this may be true, one cannot infer that a mere glucose testing—which may be inaccurate—by a sensor corresponds to achievement of glucose measurement accuracy for glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than

about 0.3 mg/L. Indeed, as clearly illustrated in FIG. 7 of Rhodes, the sensor function (which corresponds to sensor linearity in the Rhodes experiment) of the Rhodes device starts to drop precipitously at about 0.5 mg/L O_2 concentration for the silicone membrane, at about 1 mg/L O_2 concentration for the control membrane, and at about 1.5 mg/L O_2 concentration for the polyurethane membrane. Accordingly, the Patent Owner submits that Rhodes does not teach a glucose sensor system configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L, as recited in Claim 28. For at least this reason, the Patent Owner submits that the anticipatory rejection of Claims 28-30, 33, 35-39 and 41 is improper. Accordingly, withdrawal of this anticipatory rejection is respectfully requested.

B. Claims 3, 22, and 34 are patentable over Rhodes in view of Jung.

Claims 3, 22, and 34 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Rhodes in view of U.S. Patent Publication No. 2004/0173472 ("Jung"). The Patent Owner respectfully traverses this obviousness rejection.

It is well settled that the Examiner "bears the initial burden of presenting a *prima facie* case of unpatentability…" *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007). Until the Examiner has established a *prima facie* case of obviousness, Applicants need not present arguments or evidence of non-obviousness. To establish a *prima facie* case of obviousness, the Examiner must establish at least three elements. First, the prior art reference (or references when combined) must teach or suggest all of the claim limitations: "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 165 U.S.P.Q. 494, 496 (CCPA 1970); *see also M.P.E.P. § 2143.03*. Second, there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091 (Fed. Cir. 1986); *see also M.P.E.P. § 2143.02*. And finally, the Examiner must articulate some reason to modify or combine the cited references that renders the claim obvious. Merely establishing that the claimed elements can be found in the prior art is not sufficient to establish a *prima facie* case of obviousness:

> As is clear from cases such as *Adams,* a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (emphasis added).

Instead, the Court has made clear that the Examiner must establish a reason one of skill in the art would have combined the elements of the prior art, and that such reason must be more than a conclusory statement that it would have been obvious.

Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. *See In re Kahn,* 441 F.3d 977, 988 (C.A.Fed.2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-1741 (2007) (emphasis added).

As described above, the Patent Owner submits that Rhodes does not teach a glucose sensor system that is a transcutaneous system with an *in vivo* portion and an *ex vivo* portion, as recited in Claims 1, 12, and 28, from which Claims 3, 22, and 34 depend, respectively. In addition, with specific regard to Claim 34, Rhodes does not teach a glucose sensor system configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L, as recited in Claim 28, from which Claim 34 depends. Jung does not remedy these deficiencies of Rhodes. Rather, Jung is cited merely for teachings related to an analog to digital converter. A *prima facie* case of obviousness therefore cannot be established over Rhodes and Jung. Accordingly, the Patent Owner submits that this obviousness rejection of Claims 3, 22, and 34 cannot stand and thus should be withdrawn.

C. Claims 10, 26, and 40 are patentable over Rhodes in view of Sternberg.

Claims 10, 26, and 40 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Rhodes in view of Sternberg, *et al.*, Covalent Enzyme Coupling on Cellulose Acetate Membranes for Glucose Sensor Development, *Analytical Chemistry*, 60: 2781-2786 (1988) ("Sternberg"). The Patent Owner respectfully traverses this obviousness rejection. The criteria for establishing a *prima facie* case of obviousness are set forth above.

As described above, the Patent Owner submits that Rhodes does not teach a glucose sensor system that is a transcutaneous system with an *in vivo* portion and an *ex vivo* portion, as

recited in Claims 1, 12, and 28, from which Claims 10, 26, and 40 depend, respectively. In addition, with specific regard to Claim 40, Rhodes does not teach a glucose sensor system configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L, as recited in Claim 28, from which Claim 40 depends. Sternberg does not remedy these deficiencies of Rhodes. Rather, Sternberg is cited merely for teachings related to enzyme consumption over a period of continuous operation. A *prima facie* case of obviousness therefore cannot be established over Rhodes and Sternberg. Accordingly, the Patent Owner submits that this obviousness rejection of Claims 10, 26, and 40 cannot stand and thus should be withdrawn.

D. Claims 1, 2, 4-9, 11-21, 23-25, 27-33, 35-39 and 41 are patentable over Rhodes in view of Kusano.

Claims 1, 2, 4-9, 11-21, 23-25, 27-33, 35-39, and 41 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Rhodes in view of Kusano, H., Glucose enzyme electrode with percutaneous interface which operates independently of dissolved oxygen, *Clin. Phys. Physiol. Meas.*, vol. 10, 1:1-9 (1989) ("Kusano"). The Patent Owner respectfully traverses this obviousness rejection.

In the Office Action, the Examiner alleges that "[i]t would have been obvious for one of ordinary skill in the art at the time the invention was made to modify the sensor of Rhodes to include the air intake hole of Kusano in order to provide ambient oxygen to the sensor when the oxygen concentration within the fluid is inadequate for the function of the sensor."

The Patent Owner respectfully disagrees. As acknowledged by the Examiner during the Examiner Interview of July 27, 2011, Rhodes is not a transcutaneous device, *i.e.*, "Rhodes does not include both an *in vivo* and an *ex vivo* portion." This is corroborated by FIGS. 6A and 6B of Rhodes, which shows medical device structures that are consistent with implantation of a whole device, and not with a transcutaneous implantation of a device with an *ex vivo* and an *in vivo* portion. In direct contrast, Kusano is a transcutaneous device with an *in vivo* portion and an *ex vivo* portion. Kusano relies on this transcutaneous interface to obtain access to ambient oxygen. Thus, the air intake is necessarily built into the transcutaneous interface.

The Patent Owner submits that the proposed modification of the Rhodes device to have Kusano's air intake hole would seemingly not have arrived at the claimed invention. More

specifically, drilling a hole into the Rhodes device (*i.e.*, a non-transcutaneous implantable device) would not have provided a conduit to ambient oxygen. Thus, with regard to Claim 28, and claims dependent therefrom, the proposed modification would seemingly not help with respect to the claim's recited feature of accurately measuring glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L. As noted above, the Rhodes sensor function starts to drop precipitously at about 0.5 mg/L O_2 concentration for the silicone membrane.

With regard to Claims 1 and 12, and claims dependent therefrom, as described above, the Patent Owner submits that Rhodes does not teach a glucose sensor system that is a transcutaneous system with an *in vivo* portion and an *ex vivo* portion, as recited in Claims 1 and 12, from which Claims 1, 2, 4-9, 11, 13-21, 23-25, and 27 depend. While Kusano teaches a transcutaneous system with an *in vivo* portion and an *ex vivo* portion, modifying Rhodes to become a transcutaneous system would seem to be against Rhodes intended purpose of building a long-term non-transcutaneous implantable sensor. In addition, the Patent Owner submits that the Rhodes device cannot be modified to a transcutaneous device, without undue experimentation. Accordingly, a *prima facie* case of obviousness therefore cannot be established over Rhodes and Kusano.

For at least the foregoing reasons, the Patent Owner submits that this obviousness rejection of Claims 1, 2, 4-9, 11-21, 23-25, 27-33, 35-39, and 41 cannot stand and thus should be withdrawn.

E. Claims 3, 22, and 34 are patentable over Rhodes in view of Kusano and further in view of Jung.

Claims 3, 22, and 34 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Rhodes in view of Kusano and further in view of Jung. The Patent Owner respectfully traverses this obviousness rejection. The criteria for establishing a *prima facie* case of obviousness are set forth above.

As described above, the Patent Owner submits that it would not have been obvious to modify the Rhodes sensor to include the air intake hole described in Kusano. Jung does not remedy these deficiencies of Rhodes and Kusano. Rather, Jung is cited merely for teachings related to an analog to digital converter. A *prima facie* case of obviousness therefore cannot be

established over Rhodes, Kusano, and Jung. Accordingly, the Patent Owner submits that this obviousness rejection of Claims 3, 22, and 34 cannot stand and thus should be withdrawn.

F. Claims 10, 26, and 40 are patentable over Rhodes in view of Kusano and further in view of Sternberg.

Claims 10, 26, and 40 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Rhodes in view of Kusano and further in view of Sternberg. The Patent Owner respectfully traverses this obviousness rejection. The criteria for establishing a *prima facie* case of obviousness are set forth above.

As described above, the Patent Owner submits that it would not have been obvious to modify the Rhodes sensor to include the air intake hole described in Kusano. Sternberg does not remedy these deficiencies of Rhodes and Kusano. Rather, Sternberg is cited merely for teachings related to enzyme consumption over a period of continuous operation. A *prima facie* case of obviousness therefore cannot be established over Rhodes, Kusano, and Sternberg. Accordingly, the Patent Owner submits that this obviousness rejection of Claims 10, 26, and 40 cannot stand and thus should be withdrawn.

G. Claims 28-33, 37 and 41 are patentable over Kerner in view of Kusano.

Claims 28-33, 37, and 41 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Kerner in view of Kusano. The Patent Owner respectfully traverses this obviousness rejection. The criteria for establishing a *prima facie* case of obviousness are set forth above.

Kerner does not teach a glucose sensor system configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L, as recited in Claim 28. The Examiner argues, however, that "it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify the sensor of Kerner to include the air intake hole of Kusano in order to provide ambient oxygen to the sensor…"

Claim 28 has been amended to recite that the glucose sensor system is configured to use oxygen from a biological fluid surrounding the membrane to catalyze a reaction of glucose and oxygen. The Patent Owner submits that the proposed modification of the Kerner sensor to include the air intake hole of Kusano would not have necessarily led to a predictable result, nor

would it have necessarily arrived at the claimed invention. In fact, Kusano expressly states that its air intake design "[allows] **oxygen to be utilised** as mediator **from the ambient air rather than from that dissolved in the interstitial fluid**." [Bolding and underlining added for emphasis.] Kusano, at page 2. From this description, it would be readily apparent to those of ordinary skill in the art that a device that incorporates Kusano's air intake would not be configured to receive oxygen from surrounding biological fluid. More specifically, it is widely recognized in the art that the oxygen level in ambient air is much greater than the oxygen level in *in vivo* biological fluid. As a result, if the Kerner sensor is modified to have an air intake hole that supplies ambient air, as proposed by the Examiner, the oxygen would seemingly diffuse from the air intake side of the device through a membrane and toward the biological fluid side, because diffusion is a spontaneous movement of particles from a region of high concentration to a region of low concentration. Accordingly, even with the proposed modification, the oxygen used by the modified Kerner device would likely have been oxygen from the air intake (*i.e.*, from ambient air), and not necessarily (and not likely) oxygen from biological fluid. For at least the foregoing reasons, the Patent Owner respectfully submits that new Claims 28-33, 37, and 41 are distinguishable from the teachings of Kerner and Kusano. Accordingly, this obviousness rejection of Claims 28-33, 37, and 41 cannot stand, and withdrawal of this obviousness rejection is respectfully requested.

H. Claim 34 is patentable over Kerner in view of Kusano and further in view of Jung.

Claim 34 stands rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Kerner in view of Kusano and further in view of Jung. The Patent Owner respectfully traverses this obviousness rejection. The criteria for establishing a *prima facie* case of obviousness are set forth above, as are selected limitations of Claim 28, from which Claim 34 depends.

As described above, Claim 28, from which Claim 34 depends, has been amended to recite that the glucose sensor system is configured to use oxygen from a biological fluid surrounding the membrane to catalyze a reaction of glucose and oxygen. Furthermore, as described above, the Patent Owner submits that the proposed modification of the Kerner sensor to include the air intake hole of Kusano would not have necessarily led to a predictable result, nor would it have necessarily arrived at the claimed invention. Jung does not remedy these deficiencies of Kerner and Kusano. Rather, Jung is cited merely for teachings related to an analog to digital converter.

A *prima facie* case of obviousness therefore cannot be established over Kerner, Kusano, and Jung. Accordingly, the Patent Owner submits that this obviousness rejection of Claim 34 cannot stand and thus should be withdrawn.

I. Claim 40 is patentable over Kerner in view of Kusano and further in view of Sternberg.

Claim 40 stands rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Kerner in view of Kusano and further in view of Sternberg. The Patent Owner respectfully traverses this obviousness rejection. The criteria for establishing a *prima facie* case of obviousness are set forth above, as are selected limitations of Claim 28, from which Claim 40 depends.

As described above, Claim 28, from which Claim 40 depends, has been amended to recite that the glucose sensor system is configured to use oxygen from a biological fluid surrounding the membrane to catalyze a reaction of glucose and oxygen. Furthermore, as described above, the Patent Owner submits that the proposed modification of the Kerner sensor to include the air intake hole of Kusano would not have necessarily led to a predictable result, nor would it have necessarily arrived at the claimed invention. Sternberg does not remedy these deficiencies of Kerner and Kusano. Rather, Sternberg is cited merely for teachings related to enzyme consumption over a period of continuous operation. A *prima facie* case of obviousness therefore cannot be established over Kerner, Kusano, and Sternberg. Accordingly, the Patent Owner submits that this obviousness rejection of Claim 40 cannot stand and thus should be withdrawn.

J. New Claims 42 and 43 are patentable over the art cited.

New Claims 42 and 43 recite that the glucose sensor system's membrane is configured to limit transport of glucose to the electrode via a substantially uniform transport of glucose across the membrane. The Patent Owner notes that the embodiment described in Rhodes as being capable of achieving relatively low oxygen performance is illustrated in FIG. 2B, which shows a sensor with a hole 35 in the membrane system. Clearly, this hole would result in non-uniformity with respect to the transport of glucose across the membrane. The Patent Owner submits that Claims 42 and 43 are distinguishable over the cited art.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Patent Owner is not conceding in this

application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Patent Owner reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Patent Owner has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Patent Owner wishes to draw the Examiner's attention to the following applications of the present application's assignee.

Docket No.	Serial No.	Title	Filed
DEXCOM.9CPDVC	07/122395	BIOLOGICAL FLUID MEASURING DEVICE	11/19/1987
DEXCOM.9CPDCP	07/216683	BIOLOGICAL FLUID MEASURING DEVICE	7/7/1988
DEXCOM.008A	08/811473	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	3/4/1997
DEXCOM.008DV1	09/447227	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	11/22/1999
DEXCOM.8DVC1	09/489588	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	1/21/2000
DEXCOM.8DVCP1	09/636369	SYSTEMS AND METHODS FOR REMOTE MONITORING AND MODULATION OF MEDICAL DEVICES	8/11/2000
DEXCOM.006A	09/916386	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	7/27/2001
DEXCOM.007A	09/916711	SENSOR HEAD FOR USE WITH IMPLANTABLE DEVICE	7/27/2001
DEXCOM.8DVCP2	09/916858	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	7/27/2001
DEXCOM.010A	10/153356	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	5/22/2002
DEXCOM.024A	10/632537	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003

DEXCOM.026A	10/633329	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003
DEXCOM.016A	10/633367	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003
DEXCOM.025A	10/633404	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003
DEXCOM.011A	10/646333	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	8/22/2003
DEXCOM.012A	10/647065	POROUS MEMBRANES FOR USE WITH IMPLANTABLE DEVICES	8/22/2003
DEXCOM.027A	10/648849	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	8/22/2003
DEXCOM.8DVC1C1	10/657843	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	9/9/2003
DEXCOM.028A	10/695636	SILICONE COMPOSITION FOR BIOCOMPATIBLE MEMBRANE	10/28/2003
DEXCOM.006C1	10/768889	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	1/29/2004
DEXCOM.037A	10/789359	INTEGRATED DELIVERY DEVICE FOR CONTINUOUS GLUCOSE SENSOR	2/26/2004
DEXCOM.045A	10/838658	IMPLANTABLE ANALYTE SENSOR	5/3/2004
DEXCOM.044A	10/838909	IMPLANTABLE ANALYTE SENSOR	5/3/2004
DEXCOM.043A	10/838912	IMPLANTABLE ANALYTE SENSOR	5/3/2004
DEXCOM.012CP1	10/842716	BIOINTERFACE MEMBRANES INCORPORATING BIOACTIVE AGENTS	5/10/2004
DEXCOM.8DV1CP	10/846150	ANALYTE MEASURING DEVICE	5/14/2004
DEXCOM.048A	10/885476	SYSTEMS AND METHODS FOR MANUFACTURE OF AN ANALYTE-MEASURING DEVICE INCLUDING A MEMBRANE SYSTEM	7/6/2004
DEXCOM.019A	10/896637	ROLLED ELECTRODE ARRAY AND ITS METHOD FOR MANUFACTURE	7/21/2004
DEXCOM.021A	10/896639	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	7/21/2004
DEXCOM.020A	10/896772	INCREASING BIAS FOR OXYGEN PRODUCTION IN AN ELECTRODE SYSTEM	7/21/2004

DEXCOM.023A	10/897312	ELECTRODE SYSTEMS FOR ELECTROCHEMICAL SENSORS	7/21/2004
DEXCOM.022A	10/897377	ELECTROCHEMICAL SENSORS INCLUDING ELECTRODE SYSTEMS WITH INCREASED OXYGEN GENERATION	7/21/2004
DEXCOM.030A	10/991353	AFFINITY DOMAIN FOR ANALYTE SENSOR	11/16/2004
DEXCOM.032A	10/991966	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	11/17/2004
DEXCOM.038A	11/004561	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	12/3/2004
DEXCOM.031A	11/007635	SYSTEMS AND METHODS FOR IMPROVING ELECTROCHEMICAL ANALYTE SENSORS	12/7/2004
DEXCOM.029A	11/007920	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	12/8/2004
DEXCOM.008DV1C	11/021046	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	12/22/2004
DEXCOM.007C1	11/021162	SENSOR HEAD FOR USE WITH IMPLANTABLE DEVICES	12/22/2004
DEXCOM.040A	11/034343	COMPOSITE MATERIAL FOR IMPLANTABLE DEVICE	1/11/2005
DEXCOM.039A	11/034344	IMPLANTABLE DEVICE WITH IMPROVED RADIO FREQUENCY CAPABILITIES	1/11/2005
DEXCOM.024C1	11/038340	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	1/18/2005
DEXCOM.8DVCP2C	11/039269	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	1/19/2005
DEXCOM.034A	11/055779	BIOINTERFACE MEMBRANE WITH MACRO- AND MICRO-ARCHITECTURE	2/9/2005
DEXCOM.051A8	11/077643	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A5	11/077693	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A4	11/077713	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A6	11/077714	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A	11/077715	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A10	11/077739	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005

DEXCOM.051A11	11/077740	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.050A	11/077759	TRANSCUTANEOUS MEDICAL DEVICE WITH VARIABLE STIFFNESS	3/10/2005
DEXCOM.051A7	11/077763	METHOD AND SYSTEMS FOR INSERTING A TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A12	11/077765	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A1	11/077883	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A9	11/078072	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A2	11/078230	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A3	11/078232	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.061A1	11/157365	TRANSCUTANEOUS ANALYTE SENSOR	6/21/2005
DEXCOM.061A	11/157746	TRANSCUTANEOUS ANALYTE SENSOR	6/21/2005
DEXCOM.061A2	11/158227	TRANSCUTANEOUS ANALYTE SENSOR	6/21/2005
DEXCOM.016C1	11/201445	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/10/2005
DEXCOM.010DV2	11/280102	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	11/16/2005
DEXCOM.010DV1	11/280672	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	11/16/2005
DEXCOM.063A	11/333837	LOW OXYGEN IN VIVO ANALYTE SENSOR	1/17/2006
DEXCOM.061CP1	11/334107	TRANSCUTANEOUS ANALYTE SENSOR	1/17/2006
DEXCOM.061CP2	11/334876	TRANSCUTANEOUS ANALYTE SENSOR	1/18/2006
DEXCOM.058A	11/335879	CELLULOSIC-BASED INTERFERENCE DOMAIN FOR AN ANALYTE SENSOR	1/18/2006
DEXCOM.077A	11/360250	ANALYTE SENSOR	2/22/2006
DEXCOM.061CP3	11/360252	ANALYTE SENSOR	2/22/2006
DEXCOM.051CP1	11/360262	ANALYTE SENSOR	2/22/2006

DEXCOM.051CP2	11/360299	ANALYTE SENSOR	2/22/2006
DEXCOM.061CP4	11/360819	ANALYTE SENSOR	2/22/2006
DEXCOM.053A	11/373628	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA FOR SENSOR CALIBRATION	3/9/2006
DEXCOM.075A	11/404417	SILICONE BASED MEMBRANES FOR USE IN IMPLANTABLE GLUCOSE SENSORS	4/14/2006
DEXCOM.010CP1	11/404418	SILICONE BASED MEMBRANES FOR USE IN IMPLANTABLE GLUCOSE SENSORS	4/14/2006
DEXCOM.054A1	11/404421	ANALYTE SENSING BIOINTERFACE	4/14/2006
DEXCOM.054A	11/404929	ANALYTE SENSING BIOINTERFACE	4/14/2006
DEXCOM.054A2	11/404946	ANALYTE SENSING BIOINTERFACE	4/14/2006
DEXCOM.021C1	11/410392	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	4/25/2006
DEXCOM.021DV1	11/410555	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	4/25/2006
DEXCOM.051CP1C1	11/411656	ANALYTE SENSOR	4/26/2006
DEXCOM.060A	11/413238	CELLULOSIC-BASED RESISTANCE DOMAIN FOR AN ANALYTE SENSOR	4/28/2006
DEXCOM.060A2	11/413242	CELLULOSIC-BASED RESISTANCE DOMAIN FOR AN ANALYTE SENSOR	4/28/2006
DEXCOM.060A1	11/413356	CELLULOSIC-BASED RESISTANCE DOMAIN FOR AN ANALYTE SENSOR	4/28/2006
DEXCOM.051C1	11/415593	TRANSCUTANEOUS ANALYTE SENSOR	5/2/2006
DEXCOM.011DV3	11/415631	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	5/2/2006
DEXCOM.051C3	11/415999	TRANSCUTANEOUS ANALYTE SENSOR	5/2/2006
DEXCOM.011DV1	11/416058	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	5/2/2006
DEXCOM.011DV2	11/416346	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	5/2/2006
DEXCOM.051C2	11/416375	TRANSCUTANEOUS ANALYTE SENSOR	5/2/2006
DEXCOM.012CP1C2	11/416734	BIOINTERFACE MEMBRANES INCORPORATING BIOACTIVE AGENTS	5/3/2006

DEXCOM.012CP1C1	11/416825	BIOINTERFACE MEMBRANES INCORPORATING BIOACTIVE AGENTS	5/3/2006
DEXCOM.051CP4	11/439559	ANALYTE SENSOR	5/23/2006
DEXCOM.051CP3	11/439630	ANALYTE SENSOR	5/23/2006
DEXCOM.051CP5	11/439800	ANALYTE SENSOR	5/23/2006
DEXCOM.61CP3CP1	11/445792	ANALYTE SENSOR	6/1/2006
DEXCOM.027CP1	11/498410	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	8/2/2006
DEXCOM.51CP3CP1	11/503367	ANALYTE SENSOR	8/10/2006
DEXCOM.27CP1CP2	11/515342	SYSTEMS AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	9/1/2006
DEXCOM.27CP1CP1	11/515443	SYSTEMS AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	9/1/2006
DEXCOM.088A	11/543396	ANALYTE SENSOR	10/4/2006
DEXCOM.088A3	11/543404	ANALYTE SENSOR	10/4/2006
DEXCOM.088A2	11/543490	ANALYTE SENSOR	10/4/2006
DEXCOM.038CP2	11/543539	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
DEXCOM.038CP3	11/543683	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
DEXCOM.038CP1	11/543707	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
DEXCOM.038CP4	11/543734	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
DEXCOM.8DCP2CC1	11/546157	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	10/10/2006
DEXCOM.012DV1	11/654135	POROUS MEMBRANES FOR USE WITH IMPLANTABLE DEVICES	1/17/2007
DEXCOM.058CP1	11/654140	MEMBRANES FOR AN ANALYTE SENSOR	1/17/2007
DEXCOM.058CP2	11/654327	MEMBRANES FOR AN ANALYTE SENSOR	1/17/2007
DEXCOM.021CP1	11/675063	ANALYTE SENSOR	2/14/2007
DEXCOM.51CP1CP1	11/681145	ANALYTE SENSOR	3/1/2007
DEXCOM.61CP2CP1	11/690752	TRANSCUTANEOUS ANALYTE SENSOR	3/23/2007
DEXCOM.088CP3	11/691424	ANALYTE SENSOR	3/26/2007

DEXCOM.088CP1	11/691426	ANALYTE SENSOR	3/26/2007
DEXCOM.088CP2	11/691432	ANALYTE SENSOR	3/26/2007
DEXCOM.088CP4	11/691466	ANALYTE SENSOR	3/26/2007
DEXCOM.38CP1CP1	11/692154	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	3/27/2007
DEXCOM.61CP2CP4	11/734178	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2007
DEXCOM.61CP2CP2	11/734184	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2007
DEXCOM.61CP2CP3	11/734203	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2007
DEXCOM.093A	11/750907	ANALYTE SENSORS HAVING A SIGNAL-TO-NOISE RATIO SUBSTANTIALLY UNAFFECTED BY NON-CONSTANT NOISE	5/18/2007
DEXCOM.27CP1CP3	11/762638	SYSTEMS AND METHODS FOR REPLACING SIGNAL DATA ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	6/13/2007
DEXCOM.028DV1	11/763215	SILICONE COMPOSITION FOR BIOCOMPATIBLE MEMBRANE	6/14/2007
DEXCOM.051C4	11/797520	TRANSCUTANEOUS ANALYTE SENSOR	5/3/2007
DEXCOM.051C5	11/797521	TRANSCUTANEOUS ANALYTE SENSOR	5/3/2007
DEXCOM.061CP2C2	11/842139	TRANSCUTANEOUS ANALYTE SENSOR	8/21/2007
DEXCOM.061C1	11/842142	TRANSCUTANEOUS ANALYTE SENSOR	8/21/2007
DEXCOM.61CP2CPC	11/842143	TRANSCUTANEOUS ANALYTE SENSOR	8/20/2007
DEXCOM.061CP4C1	11/842146	ANALYTE SENSOR	8/20/2007
DEXCOM.061A1C1	11/842148	TRANSCUTANEOUS ANALYTE SENSOR	8/21/2007
DEXCOM.61CP3CPC	11/842149	TRANCUTANEOUS ANALYTE SENSOR	8/21/2007
DEXCOM.077C1	11/842151	ANALYTE SENSOR	8/21/2007
DEXCOM.061CP2C1	11/842154	TRANSCUTANEOUS ANALYTE SENSOR	8/21/2007
DEXCOM.093C1	11/842156	ANALYTE SENSORS HAVING A SIGNAL-TO-NOISE RATIO SUBSTANTILALLY UNAFFECTED BY NON-CONSTANT NOISE	8/21/2007
DEXCOM.51P3P1C1	11/842157	ANALYTE SENSOR	8/21/2007

DEXCOM.096A	11/855101	TRANSCUTANEOUS ANALYTE SENSOR	9/13/2007
DEXCOM.38CP1CP2	11/865572	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/1/2007
DEXCOM.025C1	11/865660	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	10/1/2007
DEXCOM.051A7C1	11/925603	TRANSCUTANEOUS ANALYTE SENSOR	10/26/2007
DEXCOM.8DV1CPD2	12/037812	ANALYTE MEASURING DEVICE	2/26/2008
DEXCOM.8DV1CPD1	12/037830	ANALYTE MEASURING DEVICE	2/26/2008
DEXCOM.107A	12/054953	ANALYTE SENSOR	3/25/2008
DEXCOM.88CP1CP2	12/055078	ANALYTE SENSOR	3/25/2008
DEXCOM.106A	12/055098	SYSTEM FOR PROCESSING SIGNALS FROM TWO IN VIVO ANALYTE SENSOR SENSORS	3/25/2008
DEXCOM.88CP1CP1	12/055114	ANALYTE SENSOR	3/25/2008
DEXCOM.88CP1CP3	12/055149	ANALYTE SENSOR	3/25/2008
DEXCOM.88CP1CP4	12/055203	ANALYTE SENSOR	3/25/2008
DEXCOM.88CP1CP5	12/055227	ANALYTE SENSOR	3/25/2008
DEXCOM.024C1D2	12/098353	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/4/2008
DEXCOM.024C1D1	12/098359	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/4/2008
DEXCOM.024C1D3	12/098627	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/7/2008
DEXCOM.051A6C3	12/101790	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2008
DEXCOM.051A9C1	12/101806	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2008
DEXCOM.051A6C2	12/101810	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2008
DEXCOM.016DV1	12/102654	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/14/2008
DEXCOM.016DV2	12/102729	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/14/2008

DEXCOM.016DV3	12/102745	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/14/2008
DEXCOM.034DV1	12/103594	BIOINTERFACE WITH MACRO- AND MICRO-ARCHITECTURE	4/15/2008
DEXCOM.050C1	12/105227	TRANSCUTANEOUS MEDICAL DEVICE WITH VARIABLE STIFFNESS	4/17/2008
DEXCOM.038CP3C1	12/111062	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	4/28/2008
DEXCOM.063C2	12/113508	LOW OXYGEN IN VIVO ANALYTE SENSOR	5/1/2008
DEXCOM.063C1	12/113724	LOW OXYGEN IN VIVO ANALYTE SENSOR	5/1/2008
DEXCOM.094A2	12/133738	INTEGRATED MEDICAMENT DELIVERY DEVICE FOR USE WITH CONTINUOUS ANALYTE SENSOR	6/5/2008
DEXCOM.094A3	12/133761	INTEGRATED MEDICAMENT DELIVERY DEVICE FOR USE WITH CONTINUOUS ANALYTE SENSOR	6/5/2008
DEXCOM.094A4	12/133786	INTEGRATED MEDICAMENT DELIVERY DEVICE FOR USE WITH CONTINUOUS ANALYTE SENSOR	6/5/2008
DEXCOM.037CP1	12/133820	INTEGRATED MEDICAMENT DELIVERY DEVICE FOR USE WITH CONTINUOUS ANALYTE SENSOR	6/5/2008
DEXCOM.061A2DV1	12/137396	TRANSCUTANEOUS ANALYTE SENSOR	6/11/2008
DEXCOM.023RE	12/139305	ELECTRODE SYSTEMS FOR ELECTROCHEMICAL SENSORS	6/13/2008
DEXCOM.051A8C1	12/175391	TRANSCUTANEOUS ANALYTE SENSOR	7/17/2008
DEXCOM.032DV2	12/182008	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	7/29/2008
DEXCOM.032C1	12/182073	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	7/29/2008
DEXCOM.032DV3	12/182083	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	7/29/2008
DEXCOM.025C1C2	12/195191	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/20/2008
DEXCOM.025C1C1	12/195773	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/21/2008
DEXCOM.045DV1	12/247137	IMPLANTABLE ANALYTE SENSOR	10/7/2008

DEXCOM.051CP3DV	12/250918	ANALYTE SENSOR	10/14/2008
DEXCOM.029DV2	12/252952	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.029DV5	12/252967	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.029DV1	12/252996	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.029DV6	12/253064	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.029DV3	12/253120	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.029DV4	12/253125	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.098A	12/258235	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.099A2	12/258318	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.016CP1	12/258320	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.099A1	12/258325	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.27CP1CP4	12/258335	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.099A	12/258345	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.007C1DV1	12/260017	SENSOR HEAD FOR USE WITH IMPLANTABLE DEVICES	10/28/2008
DEXCOM.029C1	12/263993	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	11/3/2008
DEXCOM.38CPCPDV	12/264160	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	11/3/2008
DEXCOM.043DV1	12/264835	IMPLANTABLE ANALYTE SENSOR	11/4/2008
DEXCOM.88CPP5P6	12/267494	INTEGRATED DEVICE FOR CONTINUOUS IN VIVO ANALYTE DETECTION AND SIMULTANEOUS CONTROL OF AN INFUSION DEVICE	11/7/2008
DEXCOM.038CP5	12/267518	ANALYTE SENSOR	11/7/2008
DEXCOM.88CP1P1P	12/267525	ANALYTE SENSOR	11/7/2008
DEXCOM.88P1P1P2	12/267531	ANALYTE SENSOR	11/7/2008
DEXCOM.016CP2	12/267542	ANALYTE SENSOR	11/7/2008
DEXCOM.88CPP5P4	12/267544	ANALYTE SENSOR	11/7/2008
DEXCOM.88CPP5P5	12/267545	ANALYTE SENSOR	11/7/2008

DEXCOM.88CPP5P3	12/267546	ANALYTE SENSOR	11/7/2008
DEXCOM.88CPP5P2	12/267547	ANALYTE SENSOR	11/7/2008
DEXCOM.88CPP5P1	12/267548	ANALYTE SENSOR	11/7/2008
DEXCOM.051A12C1	12/273359	TRANSCUTANEOUS ANALYTE SENSOR	11/18/2008
DEXCOM.051C6	12/329496	TRANSCUTANEOUS ANALYTE SENSOR	12/5/2008
DEXCOM.038CP2C1	12/335403	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	12/15/2008
DEXCOM.027DV1	12/353787	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	1/14/2009
DEXCOM.027DV2	12/353799	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	1/14/2009
DEXCOM.061C2	12/353870	TRANSCUTANEOUS ANALYTE SENSOR	1/14/2009
DEXCOM.051C7	12/359207	TRANSCUTANEOUS ANALYTE SENSOR	1/23/2009
DEXCOM.100A	12/362194	CONTINUOUS CARDIAC MARKER SENSOR SYSTEM	1/29/2009
DEXCOM.061CP2C3	12/364786	TRANSCUTANEOUS ANALYTE SENSOR	2/3/2009
DEXCOM.101A	12/365683	CONTINUOUS MEDICAMENT SENSOR SYSTEM FOR IN VIVO USE	2/4/2009
DEXCOM.102A2	12/390205	SYSTEMS AND METHODS FOR CUSTOMIZING DELIVERY OF SENSOR DATA	2/20/2009
DEXCOM.102A3	12/390290	SYSTEMS AND METHODS FOR BLOOD GLUCOSE MONITORING AND ALERT DELIVERY	2/20/2009
DEXCOM.102A1	12/390304	SYSTEMS AND METHODS FOR PROCESSING, TRANSMITTING AND DISPLAYING SENSOR DATA	2/20/2009
DEXCOM.061DV1	12/391148	TRANSCUTANEOUS ANALYTE SENSOR	2/23/2009
DEXCOM.051C10	12/393887	TRANSCUTANEOUS ANALYTE SENSOR	2/26/2009
DEXCOM.104A2	12/413166	POLYMER MEMBRANES FOR CONTINUOUS ANALYTE SENSORS	3/27/2009
DEXCOM.104A1	12/413231	POLYMER MEMBRANES FOR CONTINUOUS ANALYTE SENSORS	3/27/2009
DEXCOM.029DV8	12/424391	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	4/15/2009

DEXCOM.029DV7	12/424403	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	4/15/2009
DEXCOM.061A1C2	12/437436	TRANSCUTANEOUS ANALYTE SENSOR	5/7/2009
DEXCOM.029DV9	12/509396	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	7/24/2009
DEXCOM.075DV1	12/511982	SILICONE BASED MEMBRANES FOR USE IN IMPLANTABLE GLUCOSE SENSORS	7/29/2009
DEXCOM.088CP4C1	12/535620	ANALYTE SENSOR	8/4/2009
DEXCOM.037DV1	12/536852	INTEGRATED DELIVERY DEVICE FOR CONTINUOUS GLUCOSE SENSOR	8/6/2009
DEXCOM.095A	12/562011	PARTICLE-CONTAINING MEMBRANE AND PARTICULATE ELECTRODE FOR ANALYTE SENSORS	9/17/2009
DEXCOM.029DV11	12/565156	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV12	12/565166	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV13	12/565173	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV10	12/565180	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV14	12/565199	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.032DV1DV	12/565205	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV15	12/565231	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV16	12/577668	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/12/2009
DEXCOM.029C4	12/577690	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/12/2009
DEXCOM.029DV17	12/577691	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/12/2009
DEXCOM.027C1	12/579339	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.027C3	12/579357	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.027C2	12/579363	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009

DEXCOM.027C7	12/579374	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.027C4	12/579385	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.027C5	12/579388	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.027C6	12/579392	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.044DV1	12/608872	IMPLANTABLE ANALYTE SENSOR	10/29/2009
DEXCOM.040DV1	12/610127	COMPOSITE MATERIAL FOR IMPLANTABLE DEVICE	10/30/2009
DEXCOM.061CP3C1	12/610866	ANALYTE SENSOR	11/2/2009
DEXCOM.038C1	12/619502	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	11/16/2009
DEXCOM.104C1	12/628095	POLYMER MEMBRANES FOR CONTINUOUS ANALYTE SENSORS	11/30/2009
DEXCOM.088CP3C2	12/630628	ANALYTE SENSOR	12/3/2009
DEXCOM.006C1C1	12/633578	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	12/8/2009
DEXCOM.025C1C3	12/633654	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/8/2009
DEXCOM.025C1C6	12/636473	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009
DEXCOM.025C1C9	12/636494	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009
DEXCOM.025C1C8	12/636540	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009
DEXCOM.025C1C5	12/636551	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009
DEXCOM.025C1C7	12/636574	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009
DEXCOM.025C1C4	12/636584	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009

DEXCOM.016C2	12/639746	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/16/2009
DEXCOM.026C1	12/639829	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/16/2009
DEXCOM.008DV1C3	12/645097	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	12/22/2009
DEXCOM.008DV1C2	12/645270	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	12/22/2009
DEXCOM.053C2	12/683724	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA FOR SENSOR CALIBRATION	1/7/2010
DEXCOM.053C1	12/683755	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA FOR SENSOR CALIBRATION	1/7/2010
DEXCOM.010DV1C1	12/688737	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	1/15/2010
DEXCOM.021C1C1	12/688763	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	1/15/2010
DEXCOM.026DV1	12/690792	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	1/20/2010
DEXCOM.058C1	12/691617	CELLULOSIC-BASED INTERFERENCE DOMAIN FOR AN ANALYTE SENSOR	1/21/2010
DEXCOM.8DCP2CCC	12/696003	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	1/28/2010
DEXCOM.088CP2C1	12/713607	ANALYTE SENSOR	2/26/2010
DEXCOM.104A1CP1	12/718299	POLYMER MEMBRANES FOR CONTINUOUS ANALYTE SENSORS	3/5/2010
DEXCOM.104A1CP2	12/718332	POLYMER MEMBRANES FOR CONTINUOUS ANALYTE SENSORS	3/5/2010
DEXCOM.051A6C4	12/728032	TRANSCUTANEOUS ANALYTE SENSOR	3/19/2010
DEXCOM.051A6C5	12/728060	TRANSCUTANEOUS ANALYTE SENSOR	3/19/2010
DEXCOM.051A6C6	12/728061	TRANSCUTANEOUS ANALYTE SENSOR	3/19/2010
DEXCOM.051A6C7	12/728082	TRANSCUTANEOUS ANALYTE SENSOR	3/19/2010
DEXCOM.51A8C1C1	12/729035	TRANSCUTANEOUS ANALYTE SENSOR	3/22/2010

DEXCOM.51A8C1C2	12/729048	TRANSCUTANEOUS ANALYTE SENSOR	3/22/2010
DEXCOM.051A10C1	12/729058	TRANSCUTANEOUS ANALYTE SENSOR	3/22/2010
DEXCOM.016C3	12/730058	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.051A10C2	12/730072	TRANSCUTANEOUS ANALYTE SENSOR	3/23/2010
DEXCOM.016C4	12/730077	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.016C6	12/730108	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.016C8	12/730123	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
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DEXCOM.016C7	12/730144	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.016C5	12/730152	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.029C5	12/731046	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	3/24/2010
DEXCOM.032C1C1	12/731965	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	3/25/2010
DEXCOM.027C8	12/731980	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	3/25/2010
DEXCOM.27CPCPC1	12/732010	SYSTEMS AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/25/2010
DEXCOM.27CPCP3C	12/732097	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	3/25/2010
DEXCOM.038CP2CC	12/748024	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	3/26/2010
DEXCOM.135A	12/748069	METHODS AND SYSTEMS FOR PROMOTING GLUCOSE MANAGEMENT	3/26/2010

DEXCOM.016C10	12/748144	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/26/2010
DEXCOM.053C3	12/748154	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA FOR SENSOR CALIBRATION	3/26/2010
DEXCOM.061A1C3	12/749139	TRANSCUTANEOUS ANALYTE SENSOR	3/29/2010
DEXCOM.38CPCPC2	12/749265	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	3/29/2010
DEXCOM.051A9C3	12/749981	TRANSCUTANEOUS ANALYTE SENSOR	3/30/2010
DEXCOM.038C3	12/760358	CALIBRATION TECHNIQUES FOR CONTINUOUS ANALYTE SENSOR	4/14/2010
DEXCOM.038C2	12/760432	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	4/14/2010
DEXCOM.8DV1C2C1	12/763013	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	4/19/2010
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DEXCOM.016C11	12/772849	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/3/2010
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DEXCOM.051A12C2	12/780723	TRANSCUTANEOUS ANALYTE SENSOR	5/14/2010
DEXCOM.051A12C3	12/780725	TRANSCUTANEOUS ANALYTE SENSOR	5/14/2010
DEXCOM.051A12C5	12/780739	TRANSCUTANEOUS ANALYTE SENSOR	5/14/2010
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DEXCOM.027C9	12/787217	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	5/25/2010

DEXCOM.016C13	12/788125	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/26/2010
DEXCOM.027C10	12/789153	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	5/27/2010
DEXCOM.027C11	12/791686	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	6/1/2010
DEXCOM.027C12	12/791791	SYSTEM AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	6/1/2010
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DEXCOM.156A	12/829264	ANALYTE SENSOR	7/1/2010
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DEXCOM.38CPCPC1	12/838691	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	7/19/2010
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DEXCOM.027D2C1	13/014910	SYSTEM AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	1/27/2011
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DEXCOM.032C3	13/092538	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	4/22/2011
DEXCOM.061P2C5	13/116871	TRANSCUTANEOUS ANALYTE SENSOR	5/26/2011
DEXCOM.025C11	13/118915	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/31/2011
DEXCOM.026D2	13/149005	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/31/2011
DEXCOM.025C12	13/149035	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/31/2011
DEXCOM.051A6P1	13/157031	TRANSCUTANEOUS ANALYTE SENSOR	6/9/2011
DEXCOM.008C4	13/166685	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	6/22/2011
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DEXCOM.029C6	13/175392	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	7/1/2011
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DEXCOM.021C3	13/187277	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	7/20/2011
DEXCOM.012D1C1	13/210338	POROUS MEMBRANES FOR USE WITH IMPLANTABLE DEVICES	8/15/2011
DEXCOM.016DV3RX	90/010988	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/10/2010
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DEXCOM.061P3X	90/011333	ANALYTE SENSOR	11/15/2010
DEXCOM.008D1C1X	90/011345	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	11/19/2010
DEXCOM.051X	90/011351	TRANSCUTANEOUS ANALYTE SENSOR	11/22/2010
DEXCOM.8D1C3X	90/011466	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	1/31/2011
DEXCOM.016AX	90/011467	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	1/31/2011
DEXCOM.63C2X	90/011468	LOW OXYGEN IN VIVO ANALYTE SENSOR	2/1/2011
DEXCOM.063X2	90/011610	LOW OXYGEN IN VIVO ANALYTE SENSOR	3/31/2011
DEXCOM.016X4	90/011635	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/8/2011
DEXCOM.031X1	90/011645	SYSTEMS AND METHODS FOR IMPROVING ELECTROCHECMICAL ANALYTE SENSORS	4/14/2011
DEXCOM.051A5X1	90/011663	TRANSCUTANEOUS ANALYTE SENSOR	4/29/2011
DEXCOM.038X1	90/011671	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	5/5/2011
DEXCOM.008X	90/011683	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	5/10/2011
DEXCOM.024X2	90/011721	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/31/2011
DEXCOM.061A1X1	90/011720	TRANSCUTANEOUS ANALYTE SENSOR	5/31/2011

DEXCOM.008X2	90/011722	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	5/31/2011
DEXCOM.008X3	90/011776	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	6/29/2011
DEXCOM.025RX	95/001038	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/17/2008
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Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the patentability of the claims should be affirmed. Should the Examiner have any remaining concerns, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 25, 2011

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent	:	US 7,899,511
Reexam. No	:	90/011,610
Filed	:	3/31/2011
For	:	LOW OXYGEN IN VIVO ANALYTE SENSOR
Examiner	:	Flanagan, Beverly M.
Art Unit	:	3993
Conf No.	:	5743

AMENDMENT

Mail Stop *Ex Parte* Reexam
Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action dated June 23, 2011 ("Office Action"), for which a response is due on August 23, 2011, the Patent Owner herewith submits a response and respectfully requests reconsideration and allowance of the pending claims in light of the remarks presented herein.

Amendment to the Claims begins on page 2 of this paper.

Summary of Interview begins on page 8 of this paper.

Claim Status and Support for Amendments begins on page 10 of this paper.

Remarks begin on page 13 of this paper.

AMENDMENT TO THE CLAIMS

1. (Amended) A transcutaneous glucose sensor system comprising:

an *in vivo* portion and an *ex vivo* portion;

wherein the *in vivo* portion comprises:

an electrode configured to measure a concentration of glucose in a host, wherein the electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2;

a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and

wherein the *ex vivo* portion comprises sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode, wherein the sensor electronics are configured to measure the current flow in at least a picoAmp range; wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL, and wherein the system is configured to measure the current flow associated with the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L.

2. (Amended) The glucose sensor system of [[claim 1]] claims 1 or 42, wherein the sensor electronics are configured to directly measure the current flow associated with the electrode.

3. (Amended) The glucose sensor system of [[claim 1]] claims 1 or 42, further comprising an analog-to-digital converter configured to translate the current flow measurement to a digital signal.

4. (Amended) The glucose sensor system of [[claim 1]] claims 1 or 42, wherein the membrane comprises a resistance domain configured with a permeability ratio of at least about 50:1 co-analyte to glucose concentration.

5. (Original) The glucose sensor system of claim 4, wherein the permeability ratio is at least about 200:1.

6. (Amended) The glucose sensor system of [[claim 1]] claims 1 or 42, wherein the membrane comprises an enzyme.

7. (Amended) The glucose sensor system of [[claim 1]] claims 1 or 42, wherein the system is configured to determine a concentration of the glucose in a biological sample via measurement of hydrogen peroxide produced by an enzyme-catalyzed reaction of glucose with oxygen.

8. (Amended) The glucose sensor system of [[claim 1]] claims 1 or 42, wherein the system is configured to have an operable life implanted within a host of at least about one week.

9. (Amended) The glucose sensor system of [[claim 1]] claims 1 or 42, wherein the system is configured to measure glucose with substantial linearity at an oxygen concentration of less than about 0.3mg/L.

10. (Amended) The glucose sensor system of [[claim 1]] claims 1 or 42, wherein the system is configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation.

11. (Amended) The glucose sensor system of [[claim 1]] claims 1 or 42, wherein the membrane comprises a polyurethane.

12. (Amended) A transcutaneous glucose sensor system comprising:

an *in vivo* portion and an *ex vivo* portion;

wherein the *in vivo* portion comprises:

an electrode configured to measure a concentration of glucose in a host;

a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and

wherein the *ex vivo* portion comprises sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode;

wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L; and wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL.

13. (Amended) The glucose sensor system of [[claim 12]] claims 12 or 43, wherein the electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2.

14. (Amended) The glucose sensor system of [[claim 12]] claims 12 or 43, wherein the membrane comprises a resistance domain configured with a permeability ratio of at least about 50:1 co-analyte to glucose concentration.

15. (Original) The glucose sensor system of claim 14, wherein the permeability ratio is at least about 200:1.

16. (Amended) The glucose sensor system of [[claim 12]] claims 12 or 43, wherein the membrane comprises an enzyme.

17. (Amended) The glucose sensor system of [[claim 12]] claims 12 or 43, wherein the glucose sensitivity is from about 1 pA/mg/dL to about 10 pA/mg/dL.

18. (Amended) The glucose sensor system of [[claim 12]] claims 12 or 43, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.15 mg/L.

19. (Amended) The glucose sensor system of [[claim 12]] claims 12 or 43, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.05 mg/L.

20. (Amended) The glucose sensor system of [[claim 12]] claims 12 or 43, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.02 mg/L.

21. (Amended) The glucose sensor system of [[claim 12]] claims 12 or 43, wherein the sensor electronics are configured to directly measure the current flow associated with the electrode.

22. (Amended) The glucose sensor system of [[claim 12]] claims 12 or 43, further comprising an analog-to-digital converter configured to translate the current flow measurement to a digital signal.

23. (Amended) The glucose sensor system of [[claim 12]] claims 12 or 43, wherein the system is configured to determine a concentration of glucose in a biological sample via measurement of hydrogen peroxide produced by an enzyme-catalyzed reaction of glucose with oxygen.

24. (Amended) The glucose sensor system of [[claim 12]] claims 12 or 43, wherein the system is configured to have an operable life implanted within a host of at least about one week.

25. (Amended) The glucose sensor system of [[claim 12]] claims 12 or 43, wherein the system is configured to measure glucose with substantial linearity at an oxygen concentration of less than about 0.3mg/L.

26. (Amended) The glucose sensor system of [[claim 12]] claims 12 or 43, wherein the system is configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation.

27. (Amended) The glucose sensor system of [[claim 12]] claims 12 or 43, wherein the membrane comprises a polyurethane.

28. (Amended) A glucose sensor system comprising:

an electrode configured to measure a concentration of glucose in a host;

a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and

sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode;

wherein the system is configured to use oxygen from a biological fluid surrounding the membrane to catalyze a reaction of glucose and oxygen, wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL, and wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L.

29. (Original) The glucose sensor system of claim 28, wherein the electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2.

30. (Original) The glucose sensor system of claim 28, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.15 mg/L.

31. (Original) The glucose sensor system of claim 28, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.05 mg/L.

32. (Original) The glucose sensor system of claim 28, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.02 mg/L.

33. (Original) The glucose sensor system of claim 28, wherein the sensor electronics are configured to directly measure the current flow associated with the electrode.

34. (Original) The glucose sensor system of claim 28, further comprising an analog-to-digital converter configured to translate the current flow measurement to a digital signal.

35. (Original) The glucose sensor system of claim 28, wherein the membrane comprises a resistance domain configured with a permeability ratio of at least about 50:1 co-analyte to glucose concentration.

36. (Original) The glucose sensor system of claim 35, wherein the permeability ratio is at least about 200:1.

37. (Original) The glucose sensor system of claim 28, wherein the membrane comprises an enzyme.

38. (Original) The glucose sensor system of claim 28, wherein the system is configured to determine a concentration of glucose in a biological sample via measurement of hydrogen peroxide produced by an enzyme-catalyzed reaction of glucose with oxygen.

39. (Original) The glucose sensor system of claim 28, wherein the system is configured to have an operable life implanted within a host of at least about one week.

40. (Original) The glucose sensor system of claim 28, wherein the system is configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation.

41. (Original) The glucose sensor system of claim 28, wherein the membrane comprises a polyurethane.

42. (New) A glucose sensor system comprising:

an electrode configured to measure a concentration of glucose in a host, wherein the electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2;

a membrane disposed over the electrode and configured to limit transport of glucose to the electrode via a substantially uniform transport of glucose across the membrane; and

sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode, wherein the sensor electronics are configured to measure the current flow in at least a picoAmp range; wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL, and wherein the system is configured to measure the current flow associated with the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L.

43. (New) A glucose sensor system comprising:

an electrode configured to measure a concentration of glucose in a host;

a membrane disposed over the electrode and configured to limit transport of glucose to the electrode via a substantially uniform transport across the membrane; and

sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode;

wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L; and wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL.

SUMMARY OF INTERVIEW

Attendees, Date and Type of Interview

The personal interview was conducted on July 27, 2011 and attended by Examiners Beverly Flanagan, Jeanne Clark, David Reip, and Andy Kashnikow and the Patent Owner's representatives Laura Johnson, Paul Lee, and Kaare Larson.

Exhibits and/or Demonstrations

N/A.

Identification of Claims Discussed

Claims 1, 12, and 28.

Identification of Art Discussed

U.S. Patent Publication No. 2003/0032874 ("Rhodes") and Kusano, H., Glucose enzyme electrode with percutaneous interface which operates independently of dissolved oxygen, *Clin. Phys. Physiol. Meas.*, vol. 10, 1:1-9 (1989) ("Kusano").

Proposed Amendments, Principal Arguments, Results of Interview, and Other Matters

The Patent Owner's representatives proposed amending Claims 1 and 12 to recite that the glucose sensor system is a transcutaneous system with an *in vivo* portion and an *ex vivo* portion or that the membrane of the system is configured to limit transport of glucose to the electrode via a substantially uniform transport across the membrane. The Examiners agreed that either amendment would overcome the Office Action's anticipatory rejection based on Rhodes. With regard to Claims 1 and 12, the Patent Owner's representatives explained that it would not have been obvious to modify the non-transcutaneous implantable device disclosed in Rhodes to include the air intake hole described in Kusano. With regard to Claim 28, the Patent Owner's representatives proposed amending the claim to clarify that the recited system is configured to use oxygen from a biological fluid surrounding the membrane. The Patent Owner's representatives explained why modifying the Kerner device to include Kusano's air intake would not have arrived at the claimed invention, because the oxygen used with such a device would be from the air intake and not from the biological fluid surrounding the membrane, due to an oxygen concentration

gradient. The Examiners agreed with this explanation and requested that the explanations presented during the interview be included in the formal response.

With regard to the *Ex Parte* Reexamination Interview Summary filed by the Examiner on August 18, 2011, the Patent Owner would respectfully like to correct the Examiner's statement that the "Rhodes' device is not subcutaneous." The Patent Owner believes that the term "subcutaneous" should have been "transcutaneous," as it was agreed upon during the interview that the Rhodes device is not a transcutaneous device.

CLAIM STATUS AND SUPPORT FOR AMENDMENTS (37 CFR 1.530(e))

1. **Pending – Amended.** Amended Claim 1 includes the limitation that the glucose sensor system is a transcutaneous system with an *in vivo* portion and an *ex vivo* portion. Support for this limitation can be found, *e.g.*, at Col. 8, Lns. 7-20 and Col. 15, Lns. 52-57 of the '511 Patent.

2. **Pending – Amended.** Claim 2 has been amended to depend from Claims 1 or 42.

3. **Pending – Amended.** Claim 3 has been amended to depend from Claims 1 or 42.

4. **Pending – Amended.** Claim 4 has been amended to depend from Claims 1 or 42.

5. **Pending – Unchanged.**

6. **Pending – Amended.** Claim 6 has been amended to depend from Claims 1 or 42.

7. **Pending – Amended.** Claim 7 has been amended to depend from Claims 1 or 42.

8. **Pending – Amended.** Claim 8 has been amended to depend from Claims 1 or 42.

9. **Pending – Amended.** Claim 9 has been amended to depend from Claims 1 or 42.

10. **Pending – Amended.** Claim 10 has been amended to depend from Claims 1 or 42.

11. **Pending – Amended.** Claim 11 has been amended to depend from Claims 1 or 42.

12. **Pending – Amended.** Amended Claim 12 includes the limitation that the glucose sensor system is a transcutaneous system with an *in vivo* portion and an *ex vivo* portion. Support for this limitation can be found, *e.g.*, at Col. 8, Lns. 7-20 and Col. 15, Lns. 52-57 of the '511 Patent.

13. **Pending – Amended.** Claim 13 has been amended to depend from Claims 12 or 43.

14. **Pending – Amended.** Claim 14 has been amended to depend from Claims 12 or 43.

15. **Pending – Unchanged.**

16. **Pending – Amended.** Claim 16 has been amended to depend from Claims 12 or 43.

17. **Pending – Amended.** Claim 17 has been amended to depend from Claims 12 or 43.

18. **Pending – Amended.** Claim 18 has been amended to depend from Claims 12 or 43.

19. **Pending – Amended.** Claim 19 has been amended to depend from Claims 12 or 43.

20. **Pending – Amended.** Claim 20 has been amended to depend from Claims 12 or 43.

21. **Pending – Amended.** Claim 21 has been amended to depend from Claims 12 or 43.

22. **Pending – Amended.** Claim 22 has been amended to depend from Claims 12 or 43.

23. **Pending – Amended.** Claim 23 has been amended to depend from Claims 12 or 43.

24. **Pending – Amended.** Claim 24 has been amended to depend from Claims 12 or 43.

25. **Pending – Amended.** Claim 25 has been amended to depend from Claims 12 or 43.

26. **Pending – Amended.** Claim 26 has been amended to depend from Claims 12 or 43.

27. **Pending – Amended.** Claim 27 has been amended to depend from Claims 12 or 43.

28. **Pending – Amended.** Amended Claim 28 includes the limitation that the glucose sensor system is configured to use oxygen from a biological fluid surrounding the membrane to catalyze a reaction of glucose and oxygen. Support for this limitation can be found, *e.g.*, at Col. 7, Lns. 37-44 and Col. 75, Ln. 63 – Col. 76, Ln. 2 of the '511 Patent.

29. **Pending – Unchanged.**

30. **Pending – Unchanged.**

31. **Pending – Unchanged.**

32. **Pending – Unchanged.**

33. **Pending – Unchanged.**

34. **Pending – Unchanged.**

35. **Pending – Unchanged.**

36. **Pending – Unchanged.**

37. **Pending – Unchanged.**

38. **Pending – Unchanged.**

39. **Pending – Unchanged.**

40. **Pending – Unchanged.**

41. **Pending – Unchanged.**

42. **Pending – New.** New Claim 42 includes the limitation that the membrane of the system is configured to limit transport of glucose to the electrode via a substantially uniform transport across the membrane. Support for this limitation can be found, *e.g.*, at Col. 7, Lns. 51-57 and Col. 70, Lns. 1-4 of the '511 Patent.

43. **Pending – New.** New Claim 43 includes the limitation that the membrane of the system is configured to limit transport of glucose to the electrode via a substantially uniform transport across the membrane. Support for this limitation can be found, *e.g.*, at Col. 7, Lns. 51-57 and Col. 70, Lns. 1-4 of the '511 Patent.

REMARKS

Claim Status

Claims 1-41 of the '511 Patent are subject to reexamination. By virtue of this Amendment, Claims 1-4, 6-14, and 16-28 have been amended, and new Claims 42 and 43 have been added. Accordingly, upon entry of this Amendment, Claims 1-43 will be pending and under reexamination.

Prior Art Rejections

A. Claims 1, 2, 4-8, 11-18, 21, 23, 24, 27-30, 33, 35-39, and 41 are patentable over Rhodes.

Claims 1, 2, 4-8, 11-18, 21, 23, 24, 27-30, 33, 35-39, and 41 stand rejected under 35 U.S.C. 102(b) as allegedly anticipated by U.S. Patent Publication No. 2003/0032874 ("Rhodes"). The Patent Owner respectfully traverses this anticipatory rejection. "A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." *See, e.g., In re Paulsen*, 31 U.S.P.Q.2d 1671 (Fed. Cir. 1994).

Claims 1 and 12, from which Claims 2, 4-8, 11, 13-18, 21, 23, 24, and 27 depend, have been amended to recite that the glucose sensor system is a transcutaneous system with an *in vivo* portion and an *ex vivo* portion. Support for this limitation can be found, *e.g.*, at Col. 8, Lns. 7-20 and Col. 15, Lns. 52-57 of the '511 Patent. As acknowledged by the Examiner during the Examiner Interview of July 27, 2011, Rhodes does not teach a glucose sensor system that is a transcutaneous system with an *in vivo* portion and an *ex vivo* portion. See *Ex Parte* Reexamination Interview Summary filed by the Examiner on August 18, 2011 (stating that "Rhodes does not include both an *in vivo* and an *ex vivo* portion"). For at least this reason, the Patent Owner submits that the anticipatory rejection of Claims 1, 2, 4-8, 11-18, 21, 23, 24, and 27 cannot stand. Accordingly, withdrawal of this anticipatory rejection is respectfully requested.

With regard to Claims 28-30, 33, 35-39, and 41, according to the Examiner, "Rhodes also teaches that testing was conducted up to a glucose concentration of 400 mg/dL, with oxygen concentration down to 0/1 mg/dL [sic] (see Example 2, page 10)." Office Action, at page 4. While this may be true, one cannot infer that a mere glucose testing—which may be inaccurate—by a sensor corresponds to achievement of glucose measurement accuracy for glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than

about 0.3 mg/L. Indeed, as clearly illustrated in FIG. 7 of Rhodes, the sensor function (which corresponds to sensor linearity in the Rhodes experiment) of the Rhodes device starts to drop precipitously at about 0.5 mg/L O_2 concentration for the silicone membrane, at about 1 mg/L O_2 concentration for the control membrane, and at about 1.5 mg/L O_2 concentration for the polyurethane membrane. Accordingly, the Patent Owner submits that Rhodes does not teach a glucose sensor system configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L, as recited in Claim 28. For at least this reason, the Patent Owner submits that the anticipatory rejection of Claims 28-30, 33, 35-39 and 41 is improper. Accordingly, withdrawal of this anticipatory rejection is respectfully requested.

B. Claims 3, 22, and 34 are patentable over Rhodes in view of Jung.

Claims 3, 22, and 34 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Rhodes in view of U.S. Patent Publication No. 2004/0173472 ("Jung"). The Patent Owner respectfully traverses this obviousness rejection.

It is well settled that the Examiner "bears the initial burden of presenting a *prima facie* case of unpatentability…" *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007). Until the Examiner has established a *prima facie* case of obviousness, Applicants need not present arguments or evidence of non-obviousness. To establish a *prima facie* case of obviousness, the Examiner must establish at least three elements. First, the prior art reference (or references when combined) must teach or suggest all of the claim limitations: "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 165 U.S.P.Q. 494, 496 (CCPA 1970); *see also M.P.E.P. § 2143.03*. Second, there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091 (Fed. Cir. 1986); *see also M.P.E.P. § 2143.02*. And finally, the Examiner must articulate some reason to modify or combine the cited references that renders the claim obvious. Merely establishing that the claimed elements can be found in the prior art is not sufficient to establish a *prima facie* case of obviousness:

> As is clear from cases such as *Adams,* a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (emphasis added).

Instead, the Court has made clear that the Examiner must establish a reason one of skill in the art would have combined the elements of the prior art, and that such reason must be more than a conclusory statement that it would have been obvious.

Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. *See In re Kahn,* 441 F.3d 977, 988 (C.A.Fed.2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness"). *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-1741 (2007) (emphasis added).

As described above, the Patent Owner submits that Rhodes does not teach a glucose sensor system that is a transcutaneous system with an *in vivo* portion and an *ex vivo* portion, as recited in Claims 1, 12, and 28, from which Claims 3, 22, and 34 depend, respectively. In addition, with specific regard to Claim 34, Rhodes does not teach a glucose sensor system configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L, as recited in Claim 28, from which Claim 34 depends. Jung does not remedy these deficiencies of Rhodes. Rather, Jung is cited merely for teachings related to an analog to digital converter. A *prima facie* case of obviousness therefore cannot be established over Rhodes and Jung. Accordingly, the Patent Owner submits that this obviousness rejection of Claims 3, 22, and 34 cannot stand and thus should be withdrawn.

C. Claims 10, 26, and 40 are patentable over Rhodes in view of Sternberg.

Claims 10, 26, and 40 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Rhodes in view of Sternberg, *et al.*, Covalent Enzyme Coupling on Cellulose Acetate Membranes for Glucose Sensor Development, *Analytical Chemistry*, 60: 2781-2786 (1988) ("Sternberg"). The Patent Owner respectfully traverses this obviousness rejection. The criteria for establishing a *prima facie* case of obviousness are set forth above.

As described above, the Patent Owner submits that Rhodes does not teach a glucose sensor system that is a transcutaneous system with an *in vivo* portion and an *ex vivo* portion, as

recited in Claims 1, 12, and 28, from which Claims 10, 26, and 40 depend, respectively. In addition, with specific regard to Claim 40, Rhodes does not teach a glucose sensor system configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L, as recited in Claim 28, from which Claim 40 depends. Sternberg does not remedy these deficiencies of Rhodes. Rather, Sternberg is cited merely for teachings related to enzyme consumption over a period of continuous operation. A *prima facie* case of obviousness therefore cannot be established over Rhodes and Sternberg. Accordingly, the Patent Owner submits that this obviousness rejection of Claims 10, 26, and 40 cannot stand and thus should be withdrawn.

D. Claims 1, 2, 4-9, 11-21, 23-25, 27-33, 35-39 and 41 are patentable over Rhodes in view of Kusano.

Claims 1, 2, 4-9, 11-21, 23-25, 27-33, 35-39, and 41 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Rhodes in view of Kusano, H., Glucose enzyme electrode with percutaneous interface which operates independently of dissolved oxygen, *Clin. Phys. Physiol. Meas.*, vol. 10, 1:1-9 (1989) ("Kusano"). The Patent Owner respectfully traverses this obviousness rejection.

In the Office Action, the Examiner alleges that "[i]t would have been obvious for one of ordinary skill in the art at the time the invention was made to modify the sensor of Rhodes to include the air intake hole of Kusano in order to provide ambient oxygen to the sensor when the oxygen concentration within the fluid is inadequate for the function of the sensor."

The Patent Owner respectfully disagrees. As acknowledged by the Examiner during the Examiner Interview of July 27, 2011, Rhodes is not a transcutaneous device, *i.e.*, "Rhodes does not include both an *in vivo* and an *ex vivo* portion." This is corroborated by FIGS. 6A and 6B of Rhodes, which shows medical device structures that are consistent with implantation of a whole device, and not with a transcutaneous implantation of a device with an *ex vivo* and an *in vivo* portion. In direct contrast, Kusano is a transcutaneous device with an *in vivo* portion and an *ex vivo* portion. Kusano relies on this transcutaneous interface to obtain access to ambient oxygen. Thus, the air intake is necessarily built into the transcutaneous interface.

The Patent Owner submits that the proposed modification of the Rhodes device to have Kusano's air intake hole would seemingly not have arrived at the claimed invention. More

specifically, drilling a hole into the Rhodes device (*i.e.*, a non-transcutaneous implantable device) would not have provided a conduit to ambient oxygen. Thus, with regard to Claim 28, and claims dependent therefrom, the proposed modification would seemingly not help with respect to the claim's recited feature of accurately measuring glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L. As noted above, the Rhodes sensor function starts to drop precipitously at about 0.5 mg/L O_2 concentration for the silicone membrane.

With regard to Claims 1 and 12, and claims dependent therefrom, as described above, the Patent Owner submits that Rhodes does not teach a glucose sensor system that is a transcutaneous system with an *in vivo* portion and an *ex vivo* portion, as recited in Claims 1 and 12, from which Claims 1, 2, 4-9, 11, 13-21, 23-25, and 27 depend. While Kusano teaches a transcutaneous system with an *in vivo* portion and an *ex vivo* portion, modifying Rhodes to become a transcutaneous system would seem to be against Rhodes intended purpose of building a long-term non-transcutaneous implantable sensor. In addition, the Patent Owner submits that the Rhodes device cannot be modified to a transcutaneous device, without undue experimentation. Accordingly, a *prima facie* case of obviousness therefore cannot be established over Rhodes and Kusano.

For at least the foregoing reasons, the Patent Owner submits that this obviousness rejection of Claims 1, 2, 4-9, 11-21, 23-25, 27-33, 35-39, and 41 cannot stand and thus should be withdrawn.

E. Claims 3, 22, and 34 are patentable over Rhodes in view of Kusano and further in view of Jung.

Claims 3, 22, and 34 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Rhodes in view of Kusano and further in view of Jung. The Patent Owner respectfully traverses this obviousness rejection. The criteria for establishing a *prima facie* case of obviousness are set forth above.

As described above, the Patent Owner submits that it would not have been obvious to modify the Rhodes sensor to include the air intake hole described in Kusano. Jung does not remedy these deficiencies of Rhodes and Kusano. Rather, Jung is cited merely for teachings related to an analog to digital converter. A *prima facie* case of obviousness therefore cannot be

established over Rhodes, Kusano, and Jung. Accordingly, the Patent Owner submits that this obviousness rejection of Claims 3, 22, and 34 cannot stand and thus should be withdrawn.

F. Claims 10, 26, and 40 are patentable over Rhodes in view of Kusano and further in view of Sternberg.

Claims 10, 26, and 40 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Rhodes in view of Kusano and further in view of Sternberg. The Patent Owner respectfully traverses this obviousness rejection. The criteria for establishing a *prima facie* case of obviousness are set forth above.

As described above, the Patent Owner submits that it would not have been obvious to modify the Rhodes sensor to include the air intake hole described in Kusano. Sternberg does not remedy these deficiencies of Rhodes and Kusano. Rather, Sternberg is cited merely for teachings related to enzyme consumption over a period of continuous operation. A *prima facie* case of obviousness therefore cannot be established over Rhodes, Kusano, and Sternberg. Accordingly, the Patent Owner submits that this obviousness rejection of Claims 10, 26, and 40 cannot stand and thus should be withdrawn.

G. Claims 28-33, 37 and 41 are patentable over Kerner in view of Kusano.

Claims 28-33, 37, and 41 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Kerner in view of Kusano. The Patent Owner respectfully traverses this obviousness rejection. The criteria for establishing a *prima facie* case of obviousness are set forth above.

Kerner does not teach a glucose sensor system configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L, as recited in Claim 28. The Examiner argues, however, that "it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify the sensor of Kerner to include the air intake hole of Kusano in order to provide ambient oxygen to the sensor…"

Claim 28 has been amended to recite that the glucose sensor system is configured to use oxygen from a biological fluid surrounding the membrane to catalyze a reaction of glucose and oxygen. The Patent Owner submits that the proposed modification of the Kerner sensor to include the air intake hole of Kusano would not have necessarily led to a predictable result, nor

would it have necessarily arrived at the claimed invention. In fact, Kusano expressly states that its air intake design "[allows] **oxygen to be utilised** as mediator **from the ambient air rather than from that dissolved in the interstitial fluid**." [Bolding and underlining added for emphasis.] Kusano, at page 2. From this description, it would be readily apparent to those of ordinary skill in the art that a device that incorporates Kusano's air intake would not be configured to receive oxygen from surrounding biological fluid. More specifically, it is widely recognized in the art that the oxygen level in ambient air is much greater than the oxygen level in *in vivo* biological fluid. As a result, if the Kerner sensor is modified to have an air intake hole that supplies ambient air, as proposed by the Examiner, the oxygen would seemingly diffuse from the air intake side of the device through a membrane and toward the biological fluid side, because diffusion is a spontaneous movement of particles from a region of high concentration to a region of low concentration. Accordingly, even with the proposed modification, the oxygen used by the modified Kerner device would likely have been oxygen from the air intake (*i.e.*, from ambient air), and not necessarily (and not likely) oxygen from biological fluid. For at least the foregoing reasons, the Patent Owner respectfully submits that new Claims 28-33, 37, and 41 are distinguishable from the teachings of Kerner and Kusano. Accordingly, this obviousness rejection of Claims 28-33, 37, and 41 cannot stand, and withdrawal of this obviousness rejection is respectfully requested.

H. Claim 34 is patentable over Kerner in view of Kusano and further in view of Jung.

Claim 34 stands rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Kerner in view of Kusano and further in view of Jung. The Patent Owner respectfully traverses this obviousness rejection. The criteria for establishing a *prima facie* case of obviousness are set forth above, as are selected limitations of Claim 28, from which Claim 34 depends.

As described above, Claim 28, from which Claim 34 depends, has been amended to recite that the glucose sensor system is configured to use oxygen from a biological fluid surrounding the membrane to catalyze a reaction of glucose and oxygen. Furthermore, as described above, the Patent Owner submits that the proposed modification of the Kerner sensor to include the air intake hole of Kusano would not have necessarily led to a predictable result, nor would it have necessarily arrived at the claimed invention. Jung does not remedy these deficiencies of Kerner and Kusano. Rather, Jung is cited merely for teachings related to an analog to digital converter.

A *prima facie* case of obviousness therefore cannot be established over Kerner, Kusano, and Jung. Accordingly, the Patent Owner submits that this obviousness rejection of Claim 34 cannot stand and thus should be withdrawn.

I. Claim 40 is patentable over Kerner in view of Kusano and further in view of Sternberg.

Claim 40 stands rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Kerner in view of Kusano and further in view of Sternberg. The Patent Owner respectfully traverses this obviousness rejection. The criteria for establishing a *prima facie* case of obviousness are set forth above, as are selected limitations of Claim 28, from which Claim 40 depends.

As described above, Claim 28, from which Claim 40 depends, has been amended to recite that the glucose sensor system is configured to use oxygen from a biological fluid surrounding the membrane to catalyze a reaction of glucose and oxygen. Furthermore, as described above, the Patent Owner submits that the proposed modification of the Kerner sensor to include the air intake hole of Kusano would not have necessarily led to a predictable result, nor would it have necessarily arrived at the claimed invention. Sternberg does not remedy these deficiencies of Kerner and Kusano. Rather, Sternberg is cited merely for teachings related to enzyme consumption over a period of continuous operation. A *prima facie* case of obviousness therefore cannot be established over Kerner, Kusano, and Sternberg. Accordingly, the Patent Owner submits that this obviousness rejection of Claim 40 cannot stand and thus should be withdrawn.

J. New Claims 42 and 43 are patentable over the art cited.

New Claims 42 and 43 recite that the glucose sensor system's membrane is configured to limit transport of glucose to the electrode via a substantially uniform transport of glucose across the membrane. The Patent Owner notes that the embodiment described in Rhodes as being capable of achieving relatively low oxygen performance is illustrated in FIG. 2B, which shows a sensor with a hole 35 in the membrane system. Clearly, this hole would result in non-uniformity with respect to the transport of glucose across the membrane. The Patent Owner submits that Claims 42 and 43 are distinguishable over the cited art.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Patent Owner is not conceding in this

application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Patent Owner reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Patent Owner has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Patent Owner wishes to draw the Examiner's attention to the following applications of the present application's assignee.

Docket No.	Serial No.	Title	Filed
DEXCOM.9CPDVC	07/122395	BIOLOGICAL FLUID MEASURING DEVICE	11/19/1987
DEXCOM.9CPDCP	07/216683	BIOLOGICAL FLUID MEASURING DEVICE	7/7/1988
DEXCOM.008A	08/811473	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	3/4/1997
DEXCOM.008DV1	09/447227	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	11/22/1999
DEXCOM.8DVC1	09/489588	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	1/21/2000
DEXCOM.8DVCP1	09/636369	SYSTEMS AND METHODS FOR REMOTE MONITORING AND MODULATION OF MEDICAL DEVICES	8/11/2000
DEXCOM.006A	09/916386	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	7/27/2001
DEXCOM.007A	09/916711	SENSOR HEAD FOR USE WITH IMPLANTABLE DEVICE	7/27/2001
DEXCOM.8DVCP2	09/916858	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	7/27/2001
DEXCOM.010A	10/153356	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	5/22/2002
DEXCOM.024A	10/632537	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003

DEXCOM.026A	10/633329	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003
DEXCOM.016A	10/633367	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003
DEXCOM.025A	10/633404	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003
DEXCOM.011A	10/646333	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	8/22/2003
DEXCOM.012A	10/647065	POROUS MEMBRANES FOR USE WITH IMPLANTABLE DEVICES	8/22/2003
DEXCOM.027A	10/648849	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	8/22/2003
DEXCOM.8DVC1C1	10/657843	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	9/9/2003
DEXCOM.028A	10/695636	SILICONE COMPOSITION FOR BIOCOMPATIBLE MEMBRANE	10/28/2003
DEXCOM.006C1	10/768889	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	1/29/2004
DEXCOM.037A	10/789359	INTEGRATED DELIVERY DEVICE FOR CONTINUOUS GLUCOSE SENSOR	2/26/2004
DEXCOM.045A	10/838658	IMPLANTABLE ANALYTE SENSOR	5/3/2004
DEXCOM.044A	10/838909	IMPLANTABLE ANALYTE SENSOR	5/3/2004
DEXCOM.043A	10/838912	IMPLANTABLE ANALYTE SENSOR	5/3/2004
DEXCOM.012CP1	10/842716	BIOINTERFACE MEMBRANES INCORPORATING BIOACTIVE AGENTS	5/10/2004
DEXCOM.8DV1CP	10/846150	ANALYTE MEASURING DEVICE	5/14/2004
DEXCOM.048A	10/885476	SYSTEMS AND METHODS FOR MANUFACTURE OF AN ANALYTE-MEASURING DEVICE INCLUDING A MEMBRANE SYSTEM	7/6/2004
DEXCOM.019A	10/896637	ROLLED ELECTRODE ARRAY AND ITS METHOD FOR MANUFACTURE	7/21/2004
DEXCOM.021A	10/896639	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	7/21/2004
DEXCOM.020A	10/896772	INCREASING BIAS FOR OXYGEN PRODUCTION IN AN ELECTRODE SYSTEM	7/21/2004

DEXCOM.023A	10/897312	ELECTRODE SYSTEMS FOR ELECTROCHEMICAL SENSORS	7/21/2004
DEXCOM.022A	10/897377	ELECTROCHEMICAL SENSORS INCLUDING ELECTRODE SYSTEMS WITH INCREASED OXYGEN GENERATION	7/21/2004
DEXCOM.030A	10/991353	AFFINITY DOMAIN FOR ANALYTE SENSOR	11/16/2004
DEXCOM.032A	10/991966	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	11/17/2004
DEXCOM.038A	11/004561	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	12/3/2004
DEXCOM.031A	11/007635	SYSTEMS AND METHODS FOR IMPROVING ELECTROCHEMICAL ANALYTE SENSORS	12/7/2004
DEXCOM.029A	11/007920	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	12/8/2004
DEXCOM.008DV1C	11/021046	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	12/22/2004
DEXCOM.007C1	11/021162	SENSOR HEAD FOR USE WITH IMPLANTABLE DEVICES	12/22/2004
DEXCOM.040A	11/034343	COMPOSITE MATERIAL FOR IMPLANTABLE DEVICE	1/11/2005
DEXCOM.039A	11/034344	IMPLANTABLE DEVICE WITH IMPROVED RADIO FREQUENCY CAPABILITIES	1/11/2005
DEXCOM.024C1	11/038340	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	1/18/2005
DEXCOM.8DVCP2C	11/039269	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	1/19/2005
DEXCOM.034A	11/055779	BIOINTERFACE MEMBRANE WITH MACRO- AND MICRO-ARCHITECTURE	2/9/2005
DEXCOM.051A8	11/077643	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A5	11/077693	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A4	11/077713	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A6	11/077714	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A	11/077715	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A10	11/077739	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005

DEXCOM.051A11	11/077740	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.050A	11/077759	TRANSCUTANEOUS MEDICAL DEVICE WITH VARIABLE STIFFNESS	3/10/2005
DEXCOM.051A7	11/077763	METHOD AND SYSTEMS FOR INSERTING A TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A12	11/077765	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A1	11/077883	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A9	11/078072	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A2	11/078230	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.051A3	11/078232	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
DEXCOM.061A1	11/157365	TRANSCUTANEOUS ANALYTE SENSOR	6/21/2005
DEXCOM.061A	11/157746	TRANSCUTANEOUS ANALYTE SENSOR	6/21/2005
DEXCOM.061A2	11/158227	TRANSCUTANEOUS ANALYTE SENSOR	6/21/2005
DEXCOM.016C1	11/201445	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/10/2005
DEXCOM.010DV2	11/280102	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	11/16/2005
DEXCOM.010DV1	11/280672	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	11/16/2005
DEXCOM.063A	11/333837	LOW OXYGEN IN VIVO ANALYTE SENSOR	1/17/2006
DEXCOM.061CP1	11/334107	TRANSCUTANEOUS ANALYTE SENSOR	1/17/2006
DEXCOM.061CP2	11/334876	TRANSCUTANEOUS ANALYTE SENSOR	1/18/2006
DEXCOM.058A	11/335879	CELLULOSIC-BASED INTERFERENCE DOMAIN FOR AN ANALYTE SENSOR	1/18/2006
DEXCOM.077A	11/360250	ANALYTE SENSOR	2/22/2006
DEXCOM.061CP3	11/360252	ANALYTE SENSOR	2/22/2006
DEXCOM.051CP1	11/360262	ANALYTE SENSOR	2/22/2006

DEXCOM.051CP2	11/360299	ANALYTE SENSOR	2/22/2006
DEXCOM.061CP4	11/360819	ANALYTE SENSOR	2/22/2006
DEXCOM.053A	11/373628	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA FOR SENSOR CALIBRATION	3/9/2006
DEXCOM.075A	11/404417	SILICONE BASED MEMBRANES FOR USE IN IMPLANTABLE GLUCOSE SENSORS	4/14/2006
DEXCOM.010CP1	11/404418	SILICONE BASED MEMBRANES FOR USE IN IMPLANTABLE GLUCOSE SENSORS	4/14/2006
DEXCOM.054A1	11/404421	ANALYTE SENSING BIOINTERFACE	4/14/2006
DEXCOM.054A	11/404929	ANALYTE SENSING BIOINTERFACE	4/14/2006
DEXCOM.054A2	11/404946	ANALYTE SENSING BIOINTERFACE	4/14/2006
DEXCOM.021C1	11/410392	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	4/25/2006
DEXCOM.021DV1	11/410555	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	4/25/2006
DEXCOM.051CP1C1	11/411656	ANALYTE SENSOR	4/26/2006
DEXCOM.060A	11/413238	CELLULOSIC-BASED RESISTANCE DOMAIN FOR AN ANALYTE SENSOR	4/28/2006
DEXCOM.060A2	11/413242	CELLULOSIC-BASED RESISTANCE DOMAIN FOR AN ANALYTE SENSOR	4/28/2006
DEXCOM.060A1	11/413356	CELLULOSIC-BASED RESISTANCE DOMAIN FOR AN ANALYTE SENSOR	4/28/2006
DEXCOM.051C1	11/415593	TRANSCUTANEOUS ANALYTE SENSOR	5/2/2006
DEXCOM.011DV3	11/415631	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	5/2/2006
DEXCOM.051C3	11/415999	TRANSCUTANEOUS ANALYTE SENSOR	5/2/2006
DEXCOM.011DV1	11/416058	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	5/2/2006
DEXCOM.011DV2	11/416346	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	5/2/2006
DEXCOM.051C2	11/416375	TRANSCUTANEOUS ANALYTE SENSOR	5/2/2006
DEXCOM.012CP1C2	11/416734	BIOINTERFACE MEMBRANES INCORPORATING BIOACTIVE AGENTS	5/3/2006

DEXCOM.012CP1C1	11/416825	BIOINTERFACE MEMBRANES INCORPORATING BIOACTIVE AGENTS	5/3/2006
DEXCOM.051CP4	11/439559	ANALYTE SENSOR	5/23/2006
DEXCOM.051CP3	11/439630	ANALYTE SENSOR	5/23/2006
DEXCOM.051CP5	11/439800	ANALYTE SENSOR	5/23/2006
DEXCOM.61CP3CP1	11/445792	ANALYTE SENSOR	6/1/2006
DEXCOM.027CP1	11/498410	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	8/2/2006
DEXCOM.51CP3CP1	11/503367	ANALYTE SENSOR	8/10/2006
DEXCOM.27CP1CP2	11/515342	SYSTEMS AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	9/1/2006
DEXCOM.27CP1CP1	11/515443	SYSTEMS AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	9/1/2006
DEXCOM.088A	11/543396	ANALYTE SENSOR	10/4/2006
DEXCOM.088A3	11/543404	ANALYTE SENSOR	10/4/2006
DEXCOM.088A2	11/543490	ANALYTE SENSOR	10/4/2006
DEXCOM.038CP2	11/543539	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
DEXCOM.038CP3	11/543683	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
DEXCOM.038CP1	11/543707	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
DEXCOM.038CP4	11/543734	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
DEXCOM.8DCP2CC1	11/546157	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	10/10/2006
DEXCOM.012DV1	11/654135	POROUS MEMBRANES FOR USE WITH IMPLANTABLE DEVICES	1/17/2007
DEXCOM.058CP1	11/654140	MEMBRANES FOR AN ANALYTE SENSOR	1/17/2007
DEXCOM.058CP2	11/654327	MEMBRANES FOR AN ANALYTE SENSOR	1/17/2007
DEXCOM.021CP1	11/675063	ANALYTE SENSOR	2/14/2007
DEXCOM.51CP1CP1	11/681145	ANALYTE SENSOR	3/1/2007
DEXCOM.61CP2CP1	11/690752	TRANSCUTANEOUS ANALYTE SENSOR	3/23/2007
DEXCOM.088CP3	11/691424	ANALYTE SENSOR	3/26/2007

DEXCOM.088CP1	11/691426	ANALYTE SENSOR	3/26/2007
DEXCOM.088CP2	11/691432	ANALYTE SENSOR	3/26/2007
DEXCOM.088CP4	11/691466	ANALYTE SENSOR	3/26/2007
DEXCOM.38CP1CP1	11/692154	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	3/27/2007
DEXCOM.61CP2CP4	11/734178	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2007
DEXCOM.61CP2CP2	11/734184	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2007
DEXCOM.61CP2CP3	11/734203	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2007
DEXCOM.093A	11/750907	ANALYTE SENSORS HAVING A SIGNAL-TO-NOISE RATIO SUBSTANTIALLY UNAFFECTED BY NON-CONSTANT NOISE	5/18/2007
DEXCOM.27CP1CP3	11/762638	SYSTEMS AND METHODS FOR REPLACING SIGNAL DATA ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	6/13/2007
DEXCOM.028DV1	11/763215	SILICONE COMPOSITION FOR BIOCOMPATIBLE MEMBRANE	6/14/2007
DEXCOM.051C4	11/797520	TRANSCUTANEOUS ANALYTE SENSOR	5/3/2007
DEXCOM.051C5	11/797521	TRANSCUTANEOUS ANALYTE SENSOR	5/3/2007
DEXCOM.061CP2C2	11/842139	TRANSCUTANEOUS ANALYTE SENSOR	8/21/2007
DEXCOM.061C1	11/842142	TRANSCUTANEOUS ANALYTE SENSOR	8/21/2007
DEXCOM.61CP2CPC	11/842143	TRANSCUTANEOUS ANALYTE SENSOR	8/20/2007
DEXCOM.061CP4C1	11/842146	ANALYTE SENSOR	8/20/2007
DEXCOM.061A1C1	11/842148	TRANSCUTANEOUS ANALYTE SENSOR	8/21/2007
DEXCOM.61CP3CPC	11/842149	TRANCUTANEOUS ANALYTE SENSOR	8/21/2007
DEXCOM.077C1	11/842151	ANALYTE SENSOR	8/21/2007
DEXCOM.061CP2C1	11/842154	TRANSCUTANEOUS ANALYTE SENSOR	8/21/2007
DEXCOM.093C1	11/842156	ANALYTE SENSORS HAVING A SIGNAL-TO-NOISE RATIO SUBSTANTILALLY UNAFFECTED BY NON-CONSTANT NOISE	8/21/2007
DEXCOM.51P3P1C1	11/842157	ANALYTE SENSOR	8/21/2007

DEXCOM.096A	11/855101	TRANSCUTANEOUS ANALYTE SENSOR	9/13/2007
DEXCOM.38CP1CP2	11/865572	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/1/2007
DEXCOM.025C1	11/865660	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	10/1/2007
DEXCOM.051A7C1	11/925603	TRANSCUTANEOUS ANALYTE SENSOR	10/26/2007
DEXCOM.8DV1CPD2	12/037812	ANALYTE MEASURING DEVICE	2/26/2008
DEXCOM.8DV1CPD1	12/037830	ANALYTE MEASURING DEVICE	2/26/2008
DEXCOM.107A	12/054953	ANALYTE SENSOR	3/25/2008
DEXCOM.88CP1CP2	12/055078	ANALYTE SENSOR	3/25/2008
DEXCOM.106A	12/055098	SYSTEM FOR PROCESSING SIGNALS FROM TWO IN VIVO ANALYTE SENSOR SENSORS	3/25/2008
DEXCOM.88CP1CP1	12/055114	ANALYTE SENSOR	3/25/2008
DEXCOM.88CP1CP3	12/055149	ANALYTE SENSOR	3/25/2008
DEXCOM.88CP1CP4	12/055203	ANALYTE SENSOR	3/25/2008
DEXCOM.88CP1CP5	12/055227	ANALYTE SENSOR	3/25/2008
DEXCOM.024C1D2	12/098353	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/4/2008
DEXCOM.024C1D1	12/098359	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/4/2008
DEXCOM.024C1D3	12/098627	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/7/2008
DEXCOM.051A6C3	12/101790	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2008
DEXCOM.051A9C1	12/101806	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2008
DEXCOM.051A6C2	12/101810	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2008
DEXCOM.016DV1	12/102654	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/14/2008
DEXCOM.016DV2	12/102729	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/14/2008

DEXCOM.016DV3	12/102745	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/14/2008
DEXCOM.034DV1	12/103594	BIOINTERFACE WITH MACRO- AND MICRO-ARCHITECTURE	4/15/2008
DEXCOM.050C1	12/105227	TRANSCUTANEOUS MEDICAL DEVICE WITH VARIABLE STIFFNESS	4/17/2008
DEXCOM.038CP3C1	12/111062	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	4/28/2008
DEXCOM.063C2	12/113508	LOW OXYGEN IN VIVO ANALYTE SENSOR	5/1/2008
DEXCOM.063C1	12/113724	LOW OXYGEN IN VIVO ANALYTE SENSOR	5/1/2008
DEXCOM.094A2	12/133738	INTEGRATED MEDICAMENT DELIVERY DEVICE FOR USE WITH CONTINUOUS ANALYTE SENSOR	6/5/2008
DEXCOM.094A3	12/133761	INTEGRATED MEDICAMENT DELIVERY DEVICE FOR USE WITH CONTINUOUS ANALYTE SENSOR	6/5/2008
DEXCOM.094A4	12/133786	INTEGRATED MEDICAMENT DELIVERY DEVICE FOR USE WITH CONTINUOUS ANALYTE SENSOR	6/5/2008
DEXCOM.037CP1	12/133820	INTEGRATED MEDICAMENT DELIVERY DEVICE FOR USE WITH CONTINUOUS ANALYTE SENSOR	6/5/2008
DEXCOM.061A2DV1	12/137396	TRANSCUTANEOUS ANALYTE SENSOR	6/11/2008
DEXCOM.023RE	12/139305	ELECTRODE SYSTEMS FOR ELECTROCHEMICAL SENSORS	6/13/2008
DEXCOM.051A8C1	12/175391	TRANSCUTANEOUS ANALYTE SENSOR	7/17/2008
DEXCOM.032DV2	12/182008	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	7/29/2008
DEXCOM.032C1	12/182073	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	7/29/2008
DEXCOM.032DV3	12/182083	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	7/29/2008
DEXCOM.025C1C2	12/195191	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/20/2008
DEXCOM.025C1C1	12/195773	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/21/2008
DEXCOM.045DV1	12/247137	IMPLANTABLE ANALYTE SENSOR	10/7/2008

DEXCOM.051CP3DV	12/250918	ANALYTE SENSOR	10/14/2008
DEXCOM.029DV2	12/252952	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.029DV5	12/252967	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.029DV1	12/252996	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.029DV6	12/253064	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.029DV3	12/253120	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.029DV4	12/253125	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/16/2008
DEXCOM.098A	12/258235	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.099A2	12/258318	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.016CP1	12/258320	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.099A1	12/258325	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.27CP1CP4	12/258335	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.099A	12/258345	SYSTEMS AND METHODS FOR PROCESSING SENSOR DATA	10/24/2008
DEXCOM.007C1DV1	12/260017	SENSOR HEAD FOR USE WITH IMPLANTABLE DEVICES	10/28/2008
DEXCOM.029C1	12/263993	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	11/3/2008
DEXCOM.38CPCPDV	12/264160	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	11/3/2008
DEXCOM.043DV1	12/264835	IMPLANTABLE ANALYTE SENSOR	11/4/2008
DEXCOM.88CPP5P6	12/267494	INTEGRATED DEVICE FOR CONTINUOUS IN VIVO ANALYTE DETECTION AND SIMULTANEOUS CONTROL OF AN INFUSION DEVICE	11/7/2008
DEXCOM.038CP5	12/267518	ANALYTE SENSOR	11/7/2008
DEXCOM.88CP1P1P	12/267525	ANALYTE SENSOR	11/7/2008
DEXCOM.88P1P1P2	12/267531	ANALYTE SENSOR	11/7/2008
DEXCOM.016CP2	12/267542	ANALYTE SENSOR	11/7/2008
DEXCOM.88CPP5P4	12/267544	ANALYTE SENSOR	11/7/2008
DEXCOM.88CPP5P5	12/267545	ANALYTE SENSOR	11/7/2008

DEXCOM.88CPP5P3	12/267546	ANALYTE SENSOR	11/7/2008
DEXCOM.88CPP5P2	12/267547	ANALYTE SENSOR	11/7/2008
DEXCOM.88CPP5P1	12/267548	ANALYTE SENSOR	11/7/2008
DEXCOM.051A12C1	12/273359	TRANSCUTANEOUS ANALYTE SENSOR	11/18/2008
DEXCOM.051C6	12/329496	TRANSCUTANEOUS ANALYTE SENSOR	12/5/2008
DEXCOM.038CP2C1	12/335403	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	12/15/2008
DEXCOM.027DV1	12/353787	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	1/14/2009
DEXCOM.027DV2	12/353799	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	1/14/2009
DEXCOM.061C2	12/353870	TRANSCUTANEOUS ANALYTE SENSOR	1/14/2009
DEXCOM.051C7	12/359207	TRANSCUTANEOUS ANALYTE SENSOR	1/23/2009
DEXCOM.100A	12/362194	CONTINUOUS CARDIAC MARKER SENSOR SYSTEM	1/29/2009
DEXCOM.061CP2C3	12/364786	TRANSCUTANEOUS ANALYTE SENSOR	2/3/2009
DEXCOM.101A	12/365683	CONTINUOUS MEDICAMENT SENSOR SYSTEM FOR IN VIVO USE	2/4/2009
DEXCOM.102A2	12/390205	SYSTEMS AND METHODS FOR CUSTOMIZING DELIVERY OF SENSOR DATA	2/20/2009
DEXCOM.102A3	12/390290	SYSTEMS AND METHODS FOR BLOOD GLUCOSE MONITORING AND ALERT DELIVERY	2/20/2009
DEXCOM.102A1	12/390304	SYSTEMS AND METHODS FOR PROCESSING, TRANSMITTING AND DISPLAYING SENSOR DATA	2/20/2009
DEXCOM.061DV1	12/391148	TRANSCUTANEOUS ANALYTE SENSOR	2/23/2009
DEXCOM.051C10	12/393887	TRANSCUTANEOUS ANALYTE SENSOR	2/26/2009
DEXCOM.104A2	12/413166	POLYMER MEMBRANES FOR CONTINUOUS ANALYTE SENSORS	3/27/2009
DEXCOM.104A1	12/413231	POLYMER MEMBRANES FOR CONTINUOUS ANALYTE SENSORS	3/27/2009
DEXCOM.029DV8	12/424391	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	4/15/2009

DEXCOM.029DV7	12/424403	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	4/15/2009
DEXCOM.061A1C2	12/437436	TRANSCUTANEOUS ANALYTE SENSOR	5/7/2009
DEXCOM.029DV9	12/509396	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	7/24/2009
DEXCOM.075DV1	12/511982	SILICONE BASED MEMBRANES FOR USE IN IMPLANTABLE GLUCOSE SENSORS	7/29/2009
DEXCOM.088CP4C1	12/535620	ANALYTE SENSOR	8/4/2009
DEXCOM.037DV1	12/536852	INTEGRATED DELIVERY DEVICE FOR CONTINUOUS GLUCOSE SENSOR	8/6/2009
DEXCOM.095A	12/562011	PARTICLE-CONTAINING MEMBRANE AND PARTICULATE ELECTRODE FOR ANALYTE SENSORS	9/17/2009
DEXCOM.029DV11	12/565156	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV12	12/565166	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV13	12/565173	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV10	12/565180	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV14	12/565199	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.032DV1DV	12/565205	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV15	12/565231	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	9/23/2009
DEXCOM.029DV16	12/577668	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/12/2009
DEXCOM.029C4	12/577690	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/12/2009
DEXCOM.029DV17	12/577691	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	10/12/2009
DEXCOM.027C1	12/579339	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.027C3	12/579357	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.027C2	12/579363	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009

DEXCOM.027C7	12/579374	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.027C4	12/579385	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.027C5	12/579388	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.027C6	12/579392	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	10/14/2009
DEXCOM.044DV1	12/608872	IMPLANTABLE ANALYTE SENSOR	10/29/2009
DEXCOM.040DV1	12/610127	COMPOSITE MATERIAL FOR IMPLANTABLE DEVICE	10/30/2009
DEXCOM.061CP3C1	12/610866	ANALYTE SENSOR	11/2/2009
DEXCOM.038C1	12/619502	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	11/16/2009
DEXCOM.104C1	12/628095	POLYMER MEMBRANES FOR CONTINUOUS ANALYTE SENSORS	11/30/2009
DEXCOM.088CP3C2	12/630628	ANALYTE SENSOR	12/3/2009
DEXCOM.006C1C1	12/633578	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	12/8/2009
DEXCOM.025C1C3	12/633654	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/8/2009
DEXCOM.025C1C6	12/636473	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009
DEXCOM.025C1C9	12/636494	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009
DEXCOM.025C1C8	12/636540	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009
DEXCOM.025C1C5	12/636551	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009
DEXCOM.025C1C7	12/636574	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009
DEXCOM.025C1C4	12/636584	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/11/2009

DEXCOM.016C2	12/639746	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/16/2009
DEXCOM.026C1	12/639829	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	12/16/2009
DEXCOM.008DV1C3	12/645097	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	12/22/2009
DEXCOM.008DV1C2	12/645270	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	12/22/2009
DEXCOM.053C2	12/683724	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA FOR SENSOR CALIBRATION	1/7/2010
DEXCOM.053C1	12/683755	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA FOR SENSOR CALIBRATION	1/7/2010
DEXCOM.010DV1C1	12/688737	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	1/15/2010
DEXCOM.021C1C1	12/688763	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	1/15/2010
DEXCOM.026DV1	12/690792	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	1/20/2010
DEXCOM.058C1	12/691617	CELLULOSIC-BASED INTERFERENCE DOMAIN FOR AN ANALYTE SENSOR	1/21/2010
DEXCOM.8DCP2CCC	12/696003	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	1/28/2010
DEXCOM.088CP2C1	12/713607	ANALYTE SENSOR	2/26/2010
DEXCOM.104A1CP1	12/718299	POLYMER MEMBRANES FOR CONTINUOUS ANALYTE SENSORS	3/5/2010
DEXCOM.104A1CP2	12/718332	POLYMER MEMBRANES FOR CONTINUOUS ANALYTE SENSORS	3/5/2010
DEXCOM.051A6C4	12/728032	TRANSCUTANEOUS ANALYTE SENSOR	3/19/2010
DEXCOM.051A6C5	12/728060	TRANSCUTANEOUS ANALYTE SENSOR	3/19/2010
DEXCOM.051A6C6	12/728061	TRANSCUTANEOUS ANALYTE SENSOR	3/19/2010
DEXCOM.051A6C7	12/728082	TRANSCUTANEOUS ANALYTE SENSOR	3/19/2010
DEXCOM.51A8C1C1	12/729035	TRANSCUTANEOUS ANALYTE SENSOR	3/22/2010

DEXCOM.51A8C1C2	12/729048	TRANSCUTANEOUS ANALYTE SENSOR	3/22/2010
DEXCOM.051A10C1	12/729058	TRANSCUTANEOUS ANALYTE SENSOR	3/22/2010
DEXCOM.016C3	12/730058	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.051A10C2	12/730072	TRANSCUTANEOUS ANALYTE SENSOR	3/23/2010
DEXCOM.016C4	12/730077	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.016C6	12/730108	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.016C8	12/730123	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.016C9	12/730132	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.016C7	12/730144	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.016C5	12/730152	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/23/2010
DEXCOM.029C5	12/731046	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	3/24/2010
DEXCOM.032C1C1	12/731965	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	3/25/2010
DEXCOM.027C8	12/731980	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	3/25/2010
DEXCOM.27CPCPC1	12/732010	SYSTEMS AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/25/2010
DEXCOM.27CPCP3C	12/732097	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	3/25/2010
DEXCOM.038CP2CC	12/748024	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	3/26/2010
DEXCOM.135A	12/748069	METHODS AND SYSTEMS FOR PROMOTING GLUCOSE MANAGEMENT	3/26/2010

DEXCOM.016C10	12/748144	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	3/26/2010
DEXCOM.053C3	12/748154	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA FOR SENSOR CALIBRATION	3/26/2010
DEXCOM.061A1C3	12/749139	TRANSCUTANEOUS ANALYTE SENSOR	3/29/2010
DEXCOM.38CPCPC2	12/749265	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	3/29/2010
DEXCOM.051A9C3	12/749981	TRANSCUTANEOUS ANALYTE SENSOR	3/30/2010
DEXCOM.038C3	12/760358	CALIBRATION TECHNIQUES FOR CONTINUOUS ANALYTE SENSOR	4/14/2010
DEXCOM.038C2	12/760432	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	4/14/2010
DEXCOM.8DV1C2C1	12/763013	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	4/19/2010
DEXCOM.8DV1C2C2	12/763016	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	4/19/2010
DEXCOM.138A	12/770618	PERFORMANCE REPORTS ASSOCIATED WITH CONTINUOUS SENSOR DATA FROM MULTIPLE ANALYSIS TIME PERIODS	4/29/2010
DEXCOM.016C12	12/772842	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/3/2010
DEXCOM.016C11	12/772849	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/3/2010
DEXCOM.051A5C1	12/775315	TRANSCUTANEOUS ANALYTE SENSOR	5/6/2010
DEXCOM.051A12C4	12/780606	TRANSCUTANEOUS ANALYTE SENSOR	5/14/2010
DEXCOM.051A12C2	12/780723	TRANSCUTANEOUS ANALYTE SENSOR	5/14/2010
DEXCOM.051A12C3	12/780725	TRANSCUTANEOUS ANALYTE SENSOR	5/14/2010
DEXCOM.051A12C5	12/780739	TRANSCUTANEOUS ANALYTE SENSOR	5/14/2010
DEXCOM.051A12C6	12/780759	TRANSCUTANEOUS ANALYTE SENSOR	5/14/2010
DEXCOM.027C9	12/787217	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	5/25/2010

DEXCOM.016C13	12/788125	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/26/2010
DEXCOM.027C10	12/789153	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	5/27/2010
DEXCOM.027C11	12/791686	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	6/1/2010
DEXCOM.027C12	12/791791	SYSTEM AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	6/1/2010
DEXCOM.88PP5P5P	12/828967	HOUSING FOR AN INTRAVASCULAR SENSOR	7/1/2010
DEXCOM.156A	12/829264	ANALYTE SENSOR	7/1/2010
DEXCOM.111A	12/829296	ANALYTE SENSORS AND METHODS OF MANUFACTURING SAME	7/1/2010
DEXCOM.111A3	12/829306	ANALYTE SENSORS AND METHODS OF MANUFACTURING SAME	7/1/2010
DEXCOM.111A2	12/829318	ANALYTE SENSORS AND METHODS OF MANUFACTURING SAME	7/1/2010
DEXCOM.157A3	12/829337	CONTINUOUS ANALYTE SENSORS AND METHODS OF MAKING SAME	7/1/2010
DEXCOM.157A	12/829339	CONTINUOUS ANALYTE SENSORS AND METHODS OF MAKING SAME	7/1/2010
DEXCOM.157A2	12/829340	CONTINUOUS ANALYTE SENSORS AND METHODS OF MAKING SAME	7/1/2010
DEXCOM.38CPCPC1	12/838691	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	7/19/2010
DEXCOM.038CP4RE	12/839260	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	7/19/2010
DEXCOM.061CP2C4	12/853235	TRANSCUTANEOUS ANALYTE SENSOR	8/9/2010
DEXCOM.096C1	12/869996	TRANSCUTANEOUS ANALYTE SENSOR	8/27/2010
DEXCOM.038C1C2	12/874031	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	9/1/2010
DEXCOM.038C1C1	12/874045	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	9/1/2010
DEXCOM.102A1C3	12/880015	SYSTEMS AND METHODS FOR PROCESSING, TRANSMITTING AND DISPLAYING SENSOR DATA	9/10/2010

DEXCOM.102A1C2	12/880026	SYSTEMS AND METHODS FOR PROCESSING, TRANSMITTING AND DISPLAYING SENSOR DATA	9/10/2010
DEXCOM.102A1C1	12/880031	SYSTEMS AND METHODS FOR PROCESSING, TRANSMITTING AND DISPLAYING SENSOR DATA	9/10/2010
DEXCOM.159A	12/893850	TRANSCUTANEOUS ANALYTE SENSOR	9/29/2010
DEXCOM.38PPDC	12/916289	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/29/2010
DEXCOM.027D2C1	13/014910	SYSTEM AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	1/27/2011
DEXCOM.027D2C2	13/014929	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	1/27/2011
DEXCOM.027D2D1	13/015208	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	1/27/2011
DEXCOM.027D2D2	13/015245	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	1/27/2011
DEXCOM.011D3C1	13/015950	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	1/28/2011
DEXCOM.027C15	13/023776	SYSTEMS AND METHODS OF REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	2/9/2011
DEXCOM.027C14	13/023835	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	2/9/2011
DEXCOM.027C13	13/023879	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	2/9/2011
DEXCOM.027C16	13/024076	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	2/9/2011
DEXCOM.027C17	13/181341	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	7/12/2011
DEXCOM.137A	13/026163	IMPROVED RECEIVERS FOR ANALYZING AND DISPLAYING SENSOR DATA	2/11/2011
DEXCOM.063C4	13/031063	LOW OXYGEN IN VIVO ANALYTE SENSOR	2/18/2011

DEXCOM.051A1C1	13/077884	TRANSCUTANEOUS ANALYTE SENSOR	3/31/2011
DEXCOM.027P2D1	13/080587	SYSTEMS AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/5/2011
DEXCOM.051A1C2	13/086160	TRANSCUTANEOUS ANALYTE SENSOR	4/13/2011
DEXCOM.032C3	13/092538	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	4/22/2011
DEXCOM.061P2C5	13/116871	TRANSCUTANEOUS ANALYTE SENSOR	5/26/2011
DEXCOM.025C11	13/118915	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/31/2011
DEXCOM.026D2	13/149005	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/31/2011
DEXCOM.025C12	13/149035	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/31/2011
DEXCOM.051A6P1	13/157031	TRANSCUTANEOUS ANALYTE SENSOR	6/9/2011
DEXCOM.008C4	13/166685	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	6/22/2011
DEXCOM.179A	13/167602	SYSTEMS AND METHODS FOR COMMUNICATING SENSOR DATA BETWEEN COMMUNICATION DEVICES	6/23/2011
DEXCOM.061P2C6	13/172640	TRANSCUTANEOUS ANALYTE SENSOR	6/29/2011
DEXCOM.029C6	13/175392	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	7/1/2011
DEXCOM.037C1	13/180396	INTEGRATED DELIVERY DEVICE FOR CONTINUOUS GLUCOSE SENSOR	7/11/2011
DEXCOM.021C3	13/187277	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	7/20/2011
DEXCOM.012D1C1	13/210338	POROUS MEMBRANES FOR USE WITH IMPLANTABLE DEVICES	8/15/2011
DEXCOM.016DV3RX	90/010988	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/10/2010
DEXCOM.016DV2RX	90/011031	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	6/14/2010

DEXCOM.006ARX	90/011067	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	6/25/2010
DEXCOM.006C1RX	90/011080	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	7/2/2010
DEXCOM.051A7RX	90/011086	METHODS AND SYSTEMS FOR INSERTING A TRANSCUTANEOUS ANALYTE SENSOR	7/8/2010
DEXCOM.010X	90/011329	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	11/12/2010
DEXCOM.012X	90/011330	POROUS MEMBRANES FOR USE WITH IMPLANTABLE DEVICES	11/12/2010
DEXCOM.061P3X	90/011333	ANALYTE SENSOR	11/15/2010
DEXCOM.008D1C1X	90/011345	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	11/19/2010
DEXCOM.051X	90/011351	TRANSCUTANEOUS ANALYTE SENSOR	11/22/2010
DEXCOM.8D1C3X	90/011466	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	1/31/2011
DEXCOM.016AX	90/011467	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	1/31/2011
DEXCOM.63C2X	90/011468	LOW OXYGEN IN VIVO ANALYTE SENSOR	2/1/2011
DEXCOM.063X2	90/011610	LOW OXYGEN IN VIVO ANALYTE SENSOR	3/31/2011
DEXCOM.016X4	90/011635	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/8/2011
DEXCOM.031X1	90/011645	SYSTEMS AND METHODS FOR IMPROVING ELECTROCHECMICAL ANALYTE SENSORS	4/14/2011
DEXCOM.051A5X1	90/011663	TRANSCUTANEOUS ANALYTE SENSOR	4/29/2011
DEXCOM.038X1	90/011671	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	5/5/2011
DEXCOM.008X	90/011683	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	5/10/2011
DEXCOM.024X2	90/011721	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	5/31/2011
DEXCOM.061A1X1	90/011720	TRANSCUTANEOUS ANALYTE SENSOR	5/31/2011

DEXCOM.008X2	90/011722	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	5/31/2011
DEXCOM.008X3	90/011776	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	6/29/2011
DEXCOM.025RX	95/001038	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/17/2008
DEXCOM.024RX	95/001039	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	4/17/2008

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the patentability of the claims should be affirmed. Should the Examiner have any remaining concerns, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 23, 2011

By: /Rose M. Thiessen/
Rose M. Thiessen
Registration No. 40,202
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/011,610	03/31/2011	7899511	DEXCOM.063X2	5743

68851 7590 08/18/2011

KNOBBE, MARTENS, OLSEN & BEAR, LLP
2040 MAIN STREET
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IRVINE, CA 92614

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 08/18/2011

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THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS

ABBOTT DIABETES CARE INC.
BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVE., SUITE 200
EAST PALO ALTO, CA 94303

Date:

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. : 90011610
PATENT NO. : 7899511
ART UNIT : 3993

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified ex parte reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the ex parte reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Ex Parte Reexamination Interview Summary	Control No.	Patent Under Reexamination	
	90/011,610	7899511	
	Examiner	Art Unit	
	BEVERLY FLANAGAN	3993	

All participants (USPTO personnel, patent owner, patent owner's representative):

(1) *BEVERLY FLANAGAN*

(2) *SPE Andres Kashnikow*

(3) *Laura Johnson; Paul Lee*

(4) *Jeanne Clark; David Reip*

Date of Interview: *27 July 2011*

Type: a)☐ Telephonic b)☐ Video Conference
c)☒ Personal (copy given to: 1)☐ patent owner 2)☒ patent owner's representative)

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____

Agreement with respect to the claims f)☒ was reached. g)☐ was not reached. h)☐ N/A.
Any other agreement(s) are set forth below under "Description of the general nature of what was agreed to..."

Claim(s) discussed: *All of record*.

Identification of prior art discussed: *Rhodes, Kusano*.

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:
Patent owner's representative proposed claim amendments that define the prior art over the applied references. Specifically, the proposed new claim limitations of a "substantially uniform gradient across the membrane", "in vivo and ex vivo portion" and "use oxygen from a biological fluid surrounding the membrane" define over Kusano and Rhodes. Rhodes' device is not subcutaneous, and thus does not include both an in vivo and an ex vivo portion. Kusano includes a "snorkel" type element that serves as an air/oxygen intake. Neither Rhodes nor Kusano teach a substantially uniform gradient across the membrane (as supported by the specification). Formal amendments will be forthcoming .

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims patentable, if available, must be attached. Also, where no copy of the amendments that would render the claims patentable is available, a summary thereof must be attached.)

A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION MUST INCLUDE PATENT OWNER'S STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. (See MPEP § 2281). IF A RESPONSE TO THE LAST OFFICE ACTION HAS ALREADY BEEN FILED, THEN PATENT OWNER IS GIVEN **ONE MONTH** FROM THIS INTERVIEW DATE TO PROVIDE THE MANDATORY STATEMENT OF THE SUBSTANCE OF THE INTERVIEW (37 CFR 1.560(b)). THE REQUIREMENT FOR PATENT OWNER'S STATEMENT CAN NOT BE WAIVED. **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**

/BMF/	/JMC/; /DOR/	

cc: Requester (if third party requester)

1. (Amended) A glucose sensor system comprising:

an electrode configured to measure a concentration of glucose in a host, wherein the electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2;

a membrane disposed over the electrode and configured to limit transport of glucose to the electrode via a substantially uniform gradient across the membrane; and

sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode, wherein the sensor electronics are configured to measure the current flow in at least a picoAmp range;

wherein the system is configured to have a glucose sensitivity of from about 1pA/mg/dL to about 25 pA/mg/dL, and wherein the system is configured to measure the current flow associated with the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L.

12. (Amended) A transcutaneous glucose sensor system comprising:

an in vivo portion and an ex vivo portion;

wherein the in vivo portion comprises:

an electrode configured to measure a concentration of glucose in a host;

a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and

wherein the ex vivo portion comprises sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode;

wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L, and wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL.

12. (Amended) A glucose sensor system comprising:

an electrode configured to measure a concentration of glucose in a host;

a membrane disposed over the electrode and configured to limit transport of glucose to the electrode via a substantially uniform gradient across the membrane; and

sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode;

wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L, and wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL.

28. (Amended) A glucose system comprising:

an electrode configured to measure a concentration of glucose in a host;

a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and

sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode;

wherein the system is configured to use oxygen from a biological fluid surrounding the membrane to catalyze a reaction of glucose and oxygen, wherein the system is configured to have a glucose sensitivity of from about 1pA/mg/dL to about 100 pA/mg/dL, and wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3mg/L.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/011,610	03/31/2011	7899511	DEXCOM.063X2	5743

68851 7590 06/23/2011

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IRVINE, CA 92614

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 06/23/2011

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Abbott Diabetes Care, Inc.
Bozicevic, Field and Francis, LLP
1900 University Ave., Suite 200
East Palo Alto, CA 94303

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. *90/011,610*.

PATENT NO. *7899511*.

ART UNIT *3993*.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Order Granting / Denying Request For Ex Parte Reexamination	Control No.	Patent Under Reexamination	
	90/011,610	7899511	
	Examiner	Art Unit	
	BEVERLY FLANAGAN	3993	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The request for *ex parte* reexamination filed *31 March 2011* has been considered and a determination has been made. An identification of the claims, the references relied upon, and the rationale supporting the determination are attached.

Attachments: a)☐ PTO-892, b)☒ PTO/SB/08, c)☐ Other: _____

1. ☒ The request for *ex parte* reexamination is GRANTED.

9/12/11 RESPONSE TIMES ARE SET AS FOLLOWS: SEE ENCLOSED OFFICE ACTION ON MERITS.

~~For Patent Owner's Statement (Optional): TWO MONTHS from the mailing date of this communication (37 CFR 1.530 (b)). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**~~

~~For Requester's Reply (optional): TWO MONTHS from the **date of service** of any timely filed Patent Owner's Statement (37 CFR 1.535). **NO EXTENSION OF THIS TIME PERIOD IS PERMITTED.** If Patent Owner does not file a timely statement under 37 CFR 1.530(b), then no reply by requester is permitted.~~

2. ☐ The request for *ex parte* reexamination is DENIED.

This decision is not appealable (35 U.S.C. 303(c)). Requester may seek review by petition to the Commissioner under 37 CFR 1.181 within ONE MONTH from the mailing date of this communication (37 CFR 1.515(c)). **EXTENSION OF TIME TO FILE SUCH A PETITION UNDER 37 CFR 1.181 ARE AVAILABLE ONLY BY PETITION TO SUSPEND OR WAIVE THE REGULATIONS UNDER 37 CFR 1.183.**

In due course, a refund under 37 CFR 1.26 (c) will be made to requester:

a) ☐ by Treasury check or,

b) ☐ by credit to Deposit Account No. _____, or

c) ☐ by credit to a credit card account, unless otherwise notified (35 U.S.C. 303(c)).

cc:Requester (if third party requester)

DECISION ON REQUEST FOR REEXAMINATION

A substantial new question of patentability affecting claims 1-41 of United States Patent Number 7,899,511 is raised by the request for *ex parte* reexamination.

Extensions of time under 37 CFR 1.136(a) will not be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that *ex parte* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extensions of time in *ex parte* reexamination proceedings are provided for in 37 CFR 1.550(c).

Service of Papers

After the filing of a request for reexamination by a third party requester, any document filed by either the patent owner or the third party requester must be served on the other party (or parties where two or more third party requester proceedings are merged) in the reexamination proceeding in the manner provided in 37 C.F.R. 1.248. See 37 C.F.R. 1.550(f).

Waiver of Right to File Patent Owner Statement

In a telephone interview on April 13, 2011, patent owner agreed to waive its right to file a patent owner's statement under 35 U.S.C. § 304 in the event reexamination was ordered for U.S. Patent No. 7,899,511.

Amendment in Reexamination Proceedings

Patent owner is notified that any proposed amendment to the specification and/or claims in this reexamination proceeding must comply with 37 C.F.R. 1.530(d)-(j), must be formally presented pursuant to 37 C.F.R. 1.52(a) and (b), and must contain any fees required by 37 C.F.R. 1.20(c).

Submissions

In order to ensure full consideration of any amendments, affidavits or declarations or other documents as evidence of patentability, such documents must be submitted in response to the first Office action on the merits (which does not result in a close of prosecution). Submissions after the second Office action on the merits, which is intended to be a final action, will be governed by the requirements of 37 C.F.R. 1.116, after final rejection and by 37 C.F.R. 41.33 after appeal, which will be strictly enforced.

Notification of Concurrent Proceedings

The patent owner is reminded of the continuing responsibility under 37 C.F.R. 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving U.S. Patent No. 7,899,511 throughout the course of this reexamination proceeding. Likewise, if present, the third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Substantial New Question

A substantial new question of patentability (SNQ) is based on the following newly submitted printed publications:

Kusano, H., Glucose enzyme electrode with percutaneous interface which operates independently of dissolved oxygen, *Clin. Phys. Physiol. Meas.*, vol. 10, 1:1-9 (1989) (hereinafter "Kusano"); and

Sternberg et al., Covalent enzyme coating on cellulose acetate membranes for glucose sensor development, *Anal. Chem.*, 60:2781-2786 (1988) (hereinafter "Sternberg").

A substantial new question of patentability (SNQ) is also based on the following previously-cited printed publications:

Rhodes et al., U.S. Patent Publication No. 2003/0032874 (hereinafter "Rhodes");

Kerner et al., A potentially implantable enzyme electrode for amperometric measurement of glucose, *Horm Metab Res Suppl.*, 20:8-13 (1989) (hereinafter "Kerner"); and

Jung et al., U.S. Patent Publication No. 2004/0173472 (hereinafter "Jung").

On November 2, 2002, Public Law 107-273 was enacted. Title III, Subtitle A, Section 13105, part (a) of the Act revised the reexamination statute by adding the following new last sentence to 35 U.S.C. 303(a) and 312(a):

> "The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office."

For any reexamination ordered on or after November 2, 2002, the effective date of the statutory revision, reliance on previously cited/considered art, i.e., "old art," does not necessarily preclude the existence of a substantial new question of patentability (SNQ) that is based exclusively on that old art. Rather, determinations on whether a SNQ exists in such an instance shall be based upon a fact-specific inquiry. In the instant case, Rhodes was cited in the previous examination, but was not applied to the claims. In addition, Rhodes was not considered in combination with Jung, Kusano and Sternberg, as is proposed in the instant request. Kerner and Jung were both considered and applied in the previous examination. However, Kerner was not considered in combination with Kusano, as is proposed in the instant request. Similarly, Jung was not considered in combination with either Rhodes, Rhodes in view of Kusano or Kerner in view of Kusano, as is proposed in the instant request. These situations provide the new light under which the Rhodes, Kerner and Jung references are considered.

A discussion of the specifics follows:

The Rhodes Reference

It is agreed that the Rhodes reference raises a SNQ as to claims 1-41 of U.S. Patent No. 7,899,511.

In regard to claims 1, 2, 12, 13, 17, 18, 21, 28-30 and 33, it is agreed that Rhodes teaches a glucose sensor system comprised of an implantable body comprising a wire electrode with a modified reactive surface, where the diameter of the wire is 0.0508 cm (converting to a surface area of 0.002 cm^2) (see pages 3 and 8-9). Rhodes also teaches modifying the wire electrode to resemble a "T" configuration at the end of the electrode, which would increase the electrochemically reactive surface area (see pages 8-9). Rhodes also teaches a multi-region membrane disposed over the electrode that includes a resistance domain configured to limit transport of glucose to the electrode (see pages 5-8 and Figs. 2A-2F). Rhodes also teaches sensor electronics operable connected to the electrode and configured to directly measure a current flow associated with the electrode in at least a picoAmp range (see pages 8-9 and Fig. 3). Rhodes also teaches that the implantable glucose sensor showed no dependence to oxygen concentrations as low at 0.1 mg/L and a sensitivity of at least 5.5 pA/mg/dL to increasing concentrations up to 400 mg/dL of glucose (see Figs. 3 and 9 and page 11). Rhodes also teaches that testing was conducted up to a glucose concentration of 400 mg/dL, with oxygen concentrations down to 0/1 mg/dL (see Example 2, page 10). ***In***

regard to claims 4, 5, 14, 15, 35 and 36, Rhodes teaches oxygen to glucose permeability ratios of approximately 200:1(see pages 6-7). ***In regard to claims 6, 16 and 37***, Rhodes teaches an enzyme configured to catalyze a reaction of glucose and oxygen (see page 7). ***In regard to claims 7, 23 and 38***, Rhodes teaches a sensor system configured to determine a concentration of the glucose in a biological sample via measurement of hydrogen peroxide produced by an enzyme-catalyzed reaction of glucose with oxygen (see Fig. 1 and pages 3 and 6). ***In regard to claims 8, 24 and 39***, Rhodes teaches implantable glucose sensors employing multi-region membranes that have enabled function of devices for over one year in vivo (see page 5). ***In regard to claims 11, 27 and 41***, Rhodes teaches a membrane comprising a polyurethane (see page 5).

The teachings identified above were present in the prosecution of the application which became U.S. Patent No. 7,899,511. However, they were not applied to the claims. There is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claim is patentable. Accordingly, Rhodes raises a substantial new question of patentability as to claims 1-41, which question has not been decided in a previous examination of U.S. Patent No. 7,899,511.

The Jung Reference

It is agreed that the Jung reference raises a SNQ as to claims 3, 22 and 34 of U.S. Patent No. 7,899,511.

In regard to claims 3, 22 and 34, it is agreed that Jung teaches how an analog to digital converter can be used in a glucose sensor to translate the current flow measurement to a digital signal (see paragraph 0034).

The teachings identified above were present in the prosecution of the application which became U.S. Patent No. 7,899,511 and were applied to the claims. However, these teachings were not considered in combination with Rhodes, as is now proposed. Accordingly, there is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claim is patentable. Accordingly, Jung raises a substantial new question of patentability as to claims 3, 22 and 34 which question has not been decided in a previous examination of U.S. Patent No. 7,899,511.

The Sternberg Reference

It is agreed that the Sternberg reference raises a SNQ as to claims 10, 26 and 40 of U.S. Patent No. 7,899,511.

In regard to claims 10, 26 and 40, it is agreed that Sternberg teaches three procedures for preparing electrodes with immobilized glucose oxidase (GOx)and examines time-dependent loss of enzymatic activity with the loss of enzyme mass from the membrane surface (see page 2784 and Fig. 5). Fig. 5 shows that the relative consumption of GOx over the first seven days of use is between about 10% and about 15%, resulting in a consumption of about 0.18-0.63 μg (prepared with procedure a), 0.42-1.3 μg (prepared with procedure b) and 0.86-1.7 μg (prepared with procedure c).

Sternberg thus teaches how to configure a system to consume a range of enzyme mass from about 0.18-1.7 μg over 7 days of continuous operation.

The teachings identified above were not present in the prosecution of the application which became U.S. Patent No. 7,899,511. Accordingly, there is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claim is patentable. Thus, Sternberg raises a substantial new question of patentability as to claims 10, 26 and 40 which question has not been decided in a previous examination of U.S. Patent No. 7,899,511.

The Kusano Reference

It is agreed that the Kusano reference raises a SNQ as to claims 1-41 of U.S. Patent No. 7,899,511.

In regard to claims 1, 6, 9, 12, 13, 16, 18-20, 25, 28-32 and 37, it is agreed that Kusano teaches glucose sensor system that is an implantable body comprising an electrode configured to measure a glucose level in a host (see Figs. 2-4 and 9 and pages 2-3). Kusano teaches a working electrode with 0.5 μg of aluminum-linked glucose oxidase immobilized at the tip of a Pt wire 0.5 mm in diameter, making the electroactive surface (the surface area of the tip of the Pt wire) 0.000304 in^2 (area = πr^2 = (3.14)(0.25 mm)^2 = 0.196 mm^2 = 0.000304 in^2) (see Abstract). Kusano teaches a membrane located over at least a portion of the electrode surface, the membrane comprising polyurethane and having a resistance domain configured to limit transport of glucose to the electrode, including an enzyme configured to catalyze a reaction of

glucose and oxygen (see Fig. 2 and pages 1-3). Kusano also teaches sensor electronics operably connected to the electrode. Kusano also teaches that the sensor system measures glucose concentrations from 0 to 500 mg/dL, in a fluid with an oxygen concentration ranging from 0 kPa (0 mmHg) to 20.5 kPa (154 mmHg) (see pages 6-7). Kusano also teaches that the electrode had a linear response to glucose concentration at an electrode output current ranging from 0 to 20nA even when the oxygen concentration of the glucose solution is zero (see Abstract and Fig. 8). Kusano also teaches that glucose concentrations of 0 to 500 mg/dL can be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (see page 8). Oxygen concentration had no effect on electrode response (see pages 6-7 and Fig 8). The sensor system of Kusano uses an air intake hole to draw ambient air into the sensor and this configures the system to measure current flow associated with the electrode, with substantial linearity, at glucose concentrations of about 400 mg/dL, even in a fluid with an oxygen concentration at 0 mg/L (see pages 2-3 and Figs. 2 and 8).

The teachings identified above were not present in the prosecution of the application which became U.S. Patent No. 7,899,511. Accordingly, there is a substantial likelihood that a reasonable examiner would consider these teachings important in deciding whether or not the claim is patentable. Thus, Kusano raises a substantial new question of patentability as to claims 1-41 which question has not been decided in a previous examination of U.S. Patent No. 7,899,511.

The Kerner Reference

It is agreed that the Kerner reference raises a SNQ as to claims 28-34, 37, 40 and 41 of U.S. Patent No. 7,899,511.

In regard to claims 28 and 33, it is agreed that Kerner teaches a glucose sensor system comprised of an implantable body comprising an electrode configured to measure a glucose level in a host (see pages 2-3 and Fig. 1). Kerner teaches a membrane disposed over the electrode, wherein the membrane includes a resistance domain configured to limit transport of glucose to the electrode and an enzyme to catalyze a reaction of glucose and oxygen (see page 6 and Fig. 1). Kerner also teaches a sensor system configured to have, in operation, a sensitivity of from about 4.1 to 4.9 nA at 100 mg/dL (41 to 49 pA/mg/dL) (see Fig. 4 and page 11). Kerner's electronics unit is configured to directly measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL (see Figs. 4 and 6 and page 11). ***In regard to claim 29***, Kerner teaches a electrode with a diameter of 0.5 mm, which equates to a surface area of 0.00196 cm^2 (see page 9). ***In regard to claim 37***, Kerner teaches a membrane disposed over the electrode that includes a resistance domain configured to limit transport of glucose to the electrode and an enzyme to catalyze a reaction of glucose and oxygen (see page 6 and Fig. 1).

The teachings identified above were present in the prosecution of the application which became U.S. Patent No. 7,899,511 and were applied to the claims. However, these teachings were not considered in combination with Kusano, as is now proposed. Accordingly, there is a substantial likelihood that a reasonable examiner would consider

these teachings important in deciding whether or not the claim is patentable.

Accordingly, Kerner raises a substantial new question of patentability as to claims 28-34, 37, 40 and 41 which question has not been decided in a previous examination of U.S. Patent No. 7,899,511.

Conclusion

Please mail any communications to:

Attn: Mail Stop "Ex Parte Reexam"
Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Please FAX any communications to:

(571) 273-9900
Central Reexamination Unit

Please hand-deliver any communications to:

Customer Service Window
Attn: Central Reexamination Unit
Randolph Building, Lobby Level
401 Dulaney Street
Alexandria, VA 22314

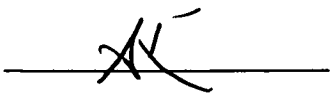
Any inquiry concerning this communication or earlier communications from the Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Signed:

/Beverly M. Flanagan/

Beverly M. Flanagan
CRU Examiner
GAU 3993
(571) 272-4766

Conferee /JRJ/

Conferee 

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application No.	90/011610
	Filing Date	03-31-2011
	First Named Inventor	Shults, Mark C.
	Art Unit	3993
(Multiple sheets used when necessary)	Examiner	Flanagan, Beverly M.
SHEET 1 OF 1	Attorney Docket No.	DEXCOM.063X2

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	6,893,552	05-17-2005	Wang et al.	
	2	7,771,352	08-10-2010	Shults, Mark et al.	
	3	7,901,354	03-08-2011	Shults, Mark et al.	
	4	2009-0099434	04-16-2009	Liu et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]
	5	WO 01/020019	03-22-2001	Implanted Biosystems		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	6	EPO Communication dated February 26, 2010 in Application No. EP 06718980.3, filed 01/17/2006	
	7	Electronic File History of Reexamination Control No. 90/011,468, filed 2/1/2011 containing Office Action(s) dated 2/14/2011 and Applicant/Third Party Submissions filed 2/1/2011 and 3/29/2011 as of March 28, 2011	

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042711

Examiner Signature	B. FLANAGAN	Date Considered	6/14/11

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T[1] - Place a check mark in this area when an English language Translation is attached.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-10)
Approved for use through 07/31/2012. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2011-03-31
First Named Inventor	Shults, Mark C.
Art Unit	
Examiner Name	
Attorney Docket Number	ADCI-GEN55

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
BJ	1	20030032874		2003-02-13	Rhodes et al.	
BJ	2	20040173472		2004-09-09	Jung et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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NON-PATENT LITERATURE DOCUMENTS

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2011-03-31
First Named Inventor	Shults, Mark C.
Art Unit	
Examiner Name	
Attorney Docket Number	ADCI-GEN55

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	Kusano, H., Glucose enzyme electrode with percutaneous interface which operates independently of dissolved oxygen, Clin. Phys. Physiol. Meas., vol. 10, 1:1-9 (1989).	☐
	2	Kerner, et al., A Potentially Implantable Enzyme Electrode for Amperometric Measurement of Glucose, Horm Metab Res Suppl., 20:8-13 (1989).	☐
	3	Sternberg, et al., Covalent Enzyme Coupling on Cellulose Acetate Membranes for Glucose Sensor Development, Anal. Chem., 60: 2781-2786 (1988).	☐

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature	B FLANAGAN	Date Considered	6/14/11

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/011,610	03/31/2011	7899511	DEXCOM.063X2	5743

68851 7590 06/23/2011

KNOBBE, MARTENS, OLSEN & BEAR, LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 06/23/2011

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

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Abbott Diabetes Care, Inc.

Bozicevic, Field and Francis, LLP

1900 University Ave., Suite 200

East Palo Alto, CA 94303

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. *90/011,610*.

PATENT NO. *7899511*.

ART UNIT *3993*.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Office Action in Ex Parte Reexamination	Control No. 90/011,610	Patent Under Reexamination 7899511	
	Examiner BEVERLY FLANAGAN	Art Unit 3993	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

a☐ Responsive to the communication(s) filed on _____ . b☐ This action is made FINAL.
c☐ A statement under 37 CFR 1.530 has not been received from the patent owner.

A shortened statutory period for response to this action is set to expire 2 month(s) from the mailing date of this letter. Failure to respond within the period for response will result in termination of the proceeding and issuance of an *ex parte* reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).** If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Information Disclosure Statement, PTO/SB/08.
3. ☐ Interview Summary, PTO-474.
4. ☐ _____.

Part II SUMMARY OF ACTION

1a. ☒ Claims *1-41* are subject to reexamination.
1b. ☐ Claims _____ are not subject to reexamination.
2. ☐ Claims _____ have been canceled in the present reexamination proceeding.
3. ☐ Claims _____ are patentable and/or confirmed.
4. ☒ Claims *1-41* are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ The drawings, filed on _____ are acceptable.
7. ☐ The proposed drawing correction, filed on _____ has been (7a)☐ approved (7b)☐ disapproved.
8. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
   a)☐ All b)☐ Some* c)☐ None of the certified copies have
   1☐ been received.
   2☐ not been received.
   3☐ been filed in Application No. _____ .
   4☐ been filed in reexamination Control No. _____.
   5☐ been received by the International Bureau in PCT application No. _____.
   * See the attached detailed Office action for a list of the certified copies not received.
9. ☐ Since the proceeding appears to be in condition for issuance of an *ex parte* reexamination certificate except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte* Quayle, 1935 C.D. 11, 453 O.G. 213.
10. ☐ Other: _____

cc: Requester (if third party requester)

DETAILED ACTION

Reexamination Procedures

In order to ensure full consideration of any amendments, affidavits or declarations, or other documents as evidence of patentability, such documents must be submitted in response to this Office action. Submissions after the next Office action, which is intended to be a final action, will be governed by the requirements of 37 C.F.R. 1.116, after final rejection and 37 C.F.R. 41.33 after appeal, which will be strictly enforced.

Extensions of time under 37 C.F.R. 1.136(a) will not be permitted in these proceedings because the provisions of 37 C.F.R. 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. § 305 requires that reexamination proceedings "will be conducted with special dispatch" (37 C.F.R. 1.550(a)). Extension of time in *ex parte* reexamination proceedings are provided for in 37 C.F.R. 1.550(c).

The patent owner is reminded of the continuing responsibility under 37 C.F.R. 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 7,899,511 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability of similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

Patent owner is notified that any proposed amendment to the specification and/or claims in this reexamination proceeding must comply with 37 C.F.R. 1.530(d)-(j), must

be formally presented pursuant to 37 C.F.R. 1.52(a) and (b), and must contain any fees required by 37 C.F.R. 1.20(c).

After the filing of a request for reexamination by a third party requester, any document filed by either the patent owner or the third party requested must be served on the other party (or parties where two or more third party requested proceedings are merged) in the reexamination proceeding in the manner provided in 37 C.F.R. 1.248. See 37 C.F.R. 1.550(f).

Waiver of Right to File Patent Owner's Statement

In a telephone interview on April 13, 2011, patent owner agreed to waive its right to file a patent owner's statement under 35 U.S.C. § 304 in the event reexamination was ordered for U.S. Patent No. 7,899,511.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-8, 11-18, 21, 23, 24, 27-30, 33, 35-39 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhodes.

In regard to claims 1, 2, 12, 13, 17, 18, 21, 28-30 and 33, it is agreed that Rhodes teaches a glucose sensor system comprised of an implantable body comprising

a wire electrode with a modified reactive surface, where the diameter of the wire is 0.0508 cm (converting to a surface area of 0.002 cm^2) (see pages 3 and 8-9). Rhodes also teaches modifying the wire electrode to resemble a "T" configuration at the end of the electrode, which would increase the electrochemically reactive surface area (see pages 8-9). Rhodes also teaches a multi-region membrane disposed over the electrode that includes a resistance domain configured to limit transport of glucose to the electrode (see pages 5-8 and Figs. 2A-2F). Rhodes also teaches sensor electronics operable connected to the electrode and configured to directly measure a current flow associated with the electrode in at least a picoAmp range (see pages 8-9 and Fig. 3). Rhodes also teaches that the implantable glucose sensor showed no dependence to oxygen concentrations as low at 0.1 mg/L and a sensitivity of at least 5.5 pA/mg/dL to increasing concentrations up to 400 mg/dL of glucose (see Figs. 3 and 9 and page 11). Rhodes also teaches that testing was conducted up to a glucose concentration of 400 mg/dL, with oxygen concentrations down to 0/1 mg/dL (see Example 2, page 10). ***In regard to claims 4, 5, 14, 15, 35 and 36***, Rhodes teaches oxygen to glucose permeability ratios of approximately 200:1(see pages 6-7). ***In regard to claims 6, 16 and 37***, Rhodes teaches an enzyme configured to catalyze a reaction of glucose and oxygen (see page 7). ***In regard to claims 7, 23 and 38***, Rhodes teaches a sensor system configured to determine a concentration of the glucose in a biological sample via measurement of hydrogen peroxide produced by an enzyme-catalyzed reaction of glucose with oxygen (see Fig. 1 and pages 3 and 6). ***In regard to claims 8, 24 and 39***, Rhodes teaches implantable glucose sensors employing multi-region membranes that

have enabled function of devices for over one year in vivo (see page 5). ***In regard to claims 11, 27 and 41***, Rhodes teaches a membrane comprising a polyurethane (see page 5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 22 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes in view of Jung.

In regard to claims 3, 22 and 34, Rhodes is silent as to an analog to digital converter configured to translate the current flow measurement into a digital signal. However, Jung teaches how an analog to digital converter can be used in a glucose sensor to translate the current flow measurement to a digital signal (see paragraph 0034). It would have been obvious for one of ordinary skill in the art at the time the invention was made to utilize an analog to digital converter, such as the one disclosed by Jung, in the device of Rhodes.

Claims 10, 26 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes in view of Sternberg.

In regard to claims 10, 26 and 40, Rhodes is silent as to the glucose sensor system being configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation. Rhodes does teach the sensor as being used in vivo for over one year and teaches the use of an immobilized glucose oxidase (GOx) as the enzyme (see paragraphs 0004 and 0127). However, Sternberg teaches three procedures for preparing electrodes with immobilized glucose oxidase (GOx) and examines time-dependent loss of enzymatic activity with the loss of enzyme mass from the membrane surface (see page 2784 and Fig. 5). Fig. 5 shows that the relative consumption of GOx over the first seven days of use is between about 10% and about 15%, resulting in a consumption of about 0.18-0.63 μg (prepared with procedure a), 0.42-1.3 μg (prepared with procedure b) and 0.86-1.7 μg (prepared with procedure c). Sternberg thus teaches how to configure a system to consume a range of enzyme mass from about 0.18-1.7 μg over 7 days of continuous operation. It would have been obvious for one of ordinary skill in the art at the time the invention was made to configure a sensor such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation, In view of the teachings of Sternberg.

Claims 1, 2, 4-9, 11-21, 23-25, 27-33, 35-39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes in view of Kusano.

In regard to claims 1, 2, 9, 12, 13, 17, 18-21, 25 and 28-33, Rhodes teaches a glucose sensor system comprised of an implantable body comprising a wire electrode with a modified reactive surface, where the diameter of the wire is 0.0508 cm

(converting to a surface area of 0.002 cm^2) (see pages 3 and 8-9). Rhodes also teaches modifying the wire electrode to resemble a "T" configuration at the end of the electrode, which would increase the electrochemically reactive surface area (see pages 8-9). Rhodes also teaches a multi-region membrane disposed over the electrode that includes a resistance domain configured to limit transport of glucose to the electrode (see pages 5-8 and Figs. 2A-2F). Rhodes also teaches sensor electronics operable connected to the electrode and configured to directly measure a current flow associated with the electrode in at least a picoAmp range (see pages 8-9 and Fig. 3). Rhodes also teaches that the implantable glucose sensor showed no dependence to oxygen concentrations as low at 0.1 mg/L and a sensitivity of at least 5.5 pA/mg/dL to increasing concentrations up to 400 mg/dL of glucose (see Figs. 3 and 9 and page 11). Rhodes also teaches that testing was conducted up to a glucose concentration of 400 mg/dL, with oxygen concentrations down to 0/1 mg/dL (see Example 2, page 10). Kusano teaches a similar glucose sensor system that is an implantable body comprising an electrode configured to measure a glucose level in a host (see Figs. 2-4 and 9 and pages 2-3). Kusano teaches a working electrode with 0.5 μg of aluminum-linked glucose oxidase immobilized at the tip of a Pt wire 0.5 mm in diameter, making the electroactive surface (the surface area of the tip of the Pt wire) 0.000304 in^2 (area = πr^2 = (3.14)(0.25 mm)^2 = 0.196 mm^2 = 0.000304 in^2) (see Abstract). Kusano teaches a membrane located over at least a portion of the electrode surface, the membrane comprising polyurethane and having a resistance domain configured to limit transport of glucose to the electrode, including an enzyme configured to catalyze a reaction of

glucose and oxygen (see Fig. 2 and pages 1-3). Kusano also teaches sensor electronics operably connected to the electrode. Kusano also teaches that the sensor system measures glucose concentrations from 0 to 500 mg/dL, in a fluid with an oxygen concentration ranging from 0 kPa (0 mmHg) to 20.5 kPa (154 mmHg) (see pages 6-7). Kusano also teaches that the electrode had a linear response to glucose concentration at an electrode output current ranging from 0 to 20nA even when the oxygen concentration of the glucose solution is zero (see Abstract and Fig. 8). Kusano also teaches that glucose concentrations of 0 to 500 mg/dL can be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (see page 8). Oxygen concentration had no effect on electrode response (see pages 6-7 and Fig 8). The sensor system of Kusano uses an air intake hole to draw ambient air into the sensor and this configures the system to measure current flow associated with the electrode, with substantial linearity, at glucose concentrations of about 400 mg/dL, even in a fluid with an oxygen concentration at 0 mg/L (see pages 2-3 and Figs. 2 and 8). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify the sensor of Rhodes to include the air intake hole of Kusano in order to provide ambient oxygen to the sensor when the oxygen concentration within the fluid is inadequate for the function of the sensor.

In regard to claims 4, 5, 14, 15, 35 and 36, Rhodes teaches oxygen to glucose permeability ratios of approximately 200:1(see pages 6-7). ***In regard to claims 6, 16 and 37***, Rhodes teaches an enzyme configured to catalyze a reaction of glucose and oxygen (see page 7). ***In regard to claims 7, 23 and 38***, Rhodes teaches a sensor

system configured to determine a concentration of the glucose in a biological sample via measurement of hydrogen peroxide produced by an enzyme-catalyzed reaction of glucose with oxygen (see Fig. 1 and pages 3 and 6). ***In regard to claims 8, 24 and 39***, Rhodes teaches implantable glucose sensors employing multi-region membranes that have enabled function of devices for over one year in vivo (see page 5). ***In regard to claims 11, 27 and 41***, Rhodes teaches a membrane comprising a polyurethane (see page 5).

Claims 3, 22 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes in view Kusano and further in view of Jung.

In regard to claims 3, 22 and 34, Rhodes is silent as to an analog to digital converter configured to translate the current flow measurement into a digital signal. However, Jung teaches how an analog to digital converter can be used in a glucose sensor to translate the current flow measurement to a digital signal (see paragraph 0034). It would have been obvious for one of ordinary skill in the art at the time the invention was made to utilize an analog to digital converter, such as the one disclosed by Jung, in the device of Rhodes.

Claims 10, 26 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes in view of Kusano and further in view of Sternberg.

In regard to claims 10, 26 and 40, Rhodes is silent as to the glucose sensor system being configured such that less than about 1 μg of enzyme is consumed over 7

days of continuous operation. Rhodes does teach the sensor as being used in vivo for over one year and teaches the use of an immobilized glucose oxidase (GOx) as the enzyme (see paragraphs 0004 and 0127). However, Sternberg teaches three procedures for preparing electrodes with immobilized glucose oxidase (GOx) and examines time-dependent loss of enzymatic activity with the loss of enzyme mass from the membrane surface (see page 2784 and Fig. 5). Fig. 5 shows that the relative consumption of GOx over the first seven days of use is between about 10% and about 15%, resulting in a consumption of about 0.18-0.63 μg (prepared with procedure a), 0.42-1.3 μg (prepared with procedure b) and 0.86-1.7 μg (prepared with procedure c). Sternberg thus teaches how to configure a system to consume a range of enzyme mass from about 0.18-1.7 μg over 7 days of continuous operation. It would have been obvious for one of ordinary skill in the art at the time the invention was made to configure a sensor such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation, in view of the teachings of Sternberg.

Claims 28-33, 37 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kerner in view of Kusano.

In regard to claims 28, 30-33 and 41, Kerner teaches a glucose sensor system comprised of an implantable body comprising an electrode configured to measure a glucose level in a host (see pages 2-3 and Fig. 1). Kerner teaches a polyurethane membrane disposed over the electrode, wherein the membrane includes a resistance domain configured to limit transport of glucose to the electrode and an enzyme to

catalyze a reaction of glucose and oxygen (see page 6 and Fig. 1). Kerner also teaches a sensor system configured to have, in operation, a sensitivity of from about 4.1 to 4.9 nA at 100 mg/dL (41 to 49 pA/mg/dL) (see Fig. 4 and page 11). Kerner's electronics unit is configured to directly measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL (see Figs. 4 and 6 and page 11). Kusano teaches a similar glucose sensor system that is an implantable body comprising an electrode configured to measure a glucose level in a host (see Figs. 2-4 and 9 and pages 2-3). Kusano teaches a working electrode with 0.5 μg of aluminum-linked glucose oxidase immobilized at the tip of a Pt wire 0.5 mm in diameter, making the electroactive surface (the surface area of the tip of the Pt wire) 0.000304 in^2 (area = πr^2 = (3.14)(0.25 mm)^2 = 0.196 mm^2 = 0.000304 in^2) (see Abstract). Kusano teaches a membrane located over at least a portion of the electrode surface, the membrane comprising polyurethane and having a resistance domain configured to limit transport of glucose to the electrode, including an enzyme configured to catalyze a reaction of glucose and oxygen (see Fig. 2 and pages 1-3). Kusano also teaches sensor electronics operably connected to the electrode. Kusano also teaches that the sensor system measures glucose concentrations from 0 to 500 mg/dL, in a fluid with an oxygen concentration ranging from 0 kPa (0 mmHg) to 20.5 kPa (154 mmHg) (see pages 6-7). Kusano also teaches that the electrode had a linear response to glucose concentration at an electrode output current ranging from 0 to 20nA even when the oxygen concentration of the glucose solution is zero (see Abstract and Fig. 8). Kusano also teaches that glucose concentrations of 0 to 500 mg/dL can be measured without

being affected by oxygen concentration in the range of 0 to 163 mmHg (see page 8). Oxygen concentration had no effect on electrode response (see pages 6-7 and Fig 8). The sensor system of Kusano uses an air intake hole to draw ambient air into the sensor and this configures the system to measure current flow associated with the electrode, with substantial linearity, at glucose concentrations of about 400 mg/dL, even in a fluid with an oxygen concentration at 0 mg/L (see pages 2-3 and Figs. 2 and 8). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify the sensor of Kerner to include the air intake hole of Kusano in order to provide ambient oxygen to the sensor when the oxygen concentration within the fluid is inadequate for the function of the sensor.

In regard to claim 29, Kerner teaches a electrode with a diameter of 0.5 mm, which equates to a surface area of 0.00196 cm^2 (see page 9). ***In regard to claim 37***, Kerner teaches a membrane disposed over the electrode that includes a resistance domain configured to limit transport of glucose to the electrode and an enzyme to catalyze a reaction of glucose and oxygen (see page 6 and Fig. 1).

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kerner in view Kusano and further in view of Jung.

In regard to claim 34, Kerner is silent as to an analog to digital converter configured to translate the current flow measurement into a digital signal. However, Jung teaches how an analog to digital converter can be used in a glucose sensor to translate the current flow measurement to a digital signal (see paragraph 0034). It

would have been obvious for one of ordinary skill in the art at the time the invention was made to utilize an analog to digital converter, such as the one disclosed by Jung, in the device of Kerner.

Claims 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kerner in view of Kusano and further in view of Sternberg.

In regard to claim 40, Kerner is silent as to the glucose sensor system being configured such that less than about 1 µg of enzyme is consumed over 7 days of continuous operation. However, Sternberg teaches three procedures for preparing electrodes with immobilized glucose oxidase (GOx) and examines time-dependent loss of enzymatic activity with the loss of enzyme mass from the membrane surface (see page 2784 and Fig. 5). Fig. 5 shows that the relative consumption of GOx over the first seven days of use is between about 10% and about 15%, resulting in a consumption of about 0.18-0.63 µg (prepared with procedure a), 0.42-1.3 µg (prepared with procedure b) and 0.86-1.7 µg (prepared with procedure c). Sternberg thus teaches how to configure a system to consume a range of enzyme mass from about 0.18-1.7 µg over 7 days of continuous operation. It would have been obvious for one of ordinary skill in the art at the time the invention was made to configure a sensor such that less than about 1 µg of enzyme is consumed over 7 days of continuous operation, in view of the teachings of Sternberg.

Conclusion

Please mail any communications to:

Attn: Mail Stop "Ex Parte Reexam"
Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Please FAX any communications to:

(571) 273-9900
Central Reexamination Unit

Please hand-deliver any communications to:

Customer Service Window
Attn: Central Reexamination Unit
Randolph Building, Lobby Level
401 Dulaney Street
Alexandria, VA 22314

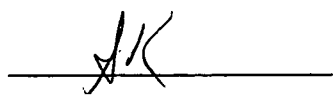
Any inquiry concerning this communication or earlier communications from the Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Signed:

/Beverly M. Flanagan/

Beverly M. Flanagan
CRU Examiner
GAU 3993
(571) 272-4766

Conferee /JRJ/

Conferee 

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/011,610	03/31/2011	7899511	ADCI-GEN55	5743

68851 7590 04/14/2011

KNOBBE, MARTENS, OLSEN & BEAR, LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 04/14/2011

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

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Alexandria, VA 22313-1450
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THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS

ABBOTT DIABETES CARE INC.
BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVE., SUITE 200
EAST PALO ALTO, CA 94303

Date: MAILED

APR 14 2011

CENTRAL REEXAMINATION UNIT

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. : 90011610
PATENT NO. : 7899511
ART UNIT : 3993

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified ex parte reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the ex parte reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Ex Parte Reexamination Interview Summary – Pilot Program for Waiver of Patent Owner's Statement	Control No. 90/011,610	Patent For Which Reexamination is Requested 7,899,511
	Examiner	Art Unit 3993

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address. --

All participants (USPTO official and patent owner):

(1) Patricia Martin, CRU (3)

(2) Rose Thiessen, 40202 (4)

Date of Telephonic Interview: 4/13/11.

The USPTO official requested waiver of the patent owner's statement pursuant to the pilot program for waiver of patent owner's statement in *ex parte* reexamination proceedings.*

☒ The patent owner **agreed** to waive its right to file a patent owner's statement under 35 U.S.C. 304 in the event reexamination is ordered for the above-identified patent.

☐ The patent owner **did not agree** to waive its right to file a patent owner's statement under 35 U.S.C. 304 at this time.

The patent owner is not required to file a written statement of this telephone communication under 37 CFR 1.560(b) or otherwise. However, any disagreement as to this interview summary must be brought to the immediate attention of the USPTO, and no later than one month from the mailing date of this interview summary. Extensions of time are governed by 37 CFR 1.550(c).

*For more information regarding this pilot program, see *Pilot Program for Waiver of Patent Owner's Statement in Ex Parte Reexamination Proceedings*, 75 *Fed. Reg.* 47269 (August 5, 2010), available on the USPTO Web site at http://www.uspto.gov/patents/law/notices/2010.jsp.

☐ USPTO personnel were unable to reach the patent owner.

The patent owner may contact the USPTO personnel at the telephone number provided below if the patent owner decides to waive the right to file a patent owner's statement under 35 U.S.C. 304.

/Patricia Martin/
Paralegal Specialist 571-272-5004
Signature and telephone number of the USPTO official who contacted or attempted to contact the patent owner.

cc: Requester (if third party requester)

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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REEXAM CONTROL NUMBER	FILING OR 371 (c) DATE	PATENT NUMBER
90/011,610	03/31/2011	7899511

CONFIRMATION NO. 5743

REEXAMINATION REQUEST NOTICE

ABBOTT DIABETES CARE INC.
BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVE., SUITE 200
EAST PALO ALTO, CA 94303

OC000000047115389

Date Mailed: 04/13/2011

NOTICE OF REEXAMINATION REQUEST FILING DATE

(Third Party Requester)

Requester is hereby notified that the filing date of the request for reexamination is 03/31/2011, the date that the filing requirements of 37 CFR § 1.510 were received.

A decision on the request for reexamination will be mailed within three months from the filing date of the request for reexamination. (See 37 CFR 1.515(a)).

A copy of the Notice is being sent to the person identified by the requester as the patent owner. Further patent owner correspondence will be the latest attorney or agent of record in the patent file. (See 37 CFR 1.33). Any paper filed should include a reference to the present request for reexamination (by Reexamination Control Number).

cc: Patent Owner
68851
KNOBBE, MARTENS, OLSEN & BEAR, LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

/sdstevenson/

Legal Instruments Examiner
Central Reexamination Unit 571-272-7705; FAX No. 571-273-9900

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REEXAM CONTROL NUMBER	FILING OR 371 (c) DATE	PATENT NUMBER
90/011,610	03/31/2011	7899511

CONFIRMATION NO. 5743

REEXAM ASSIGNMENT NOTICE

68851
KNOBBE, MARTENS, OLSEN & BEAR, LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

OC000000047115390

Date Mailed: 04/13/2011

NOTICE OF ASSIGNMENT OF REEXAMINATION REQUEST

The above-identified request for reexamination has been assigned to Art Unit 3993. All future correspondence to the proceeding should be identified by the control number listed above and directed to the assigned Art Unit.

A copy of this Notice is being sent to the latest attorney or agent of record in the patent file or to all owners of record. (See 37 CFR 1.33(c)). If the addressee is not, or does not represent, the current owner, he or she is required to forward all communications regarding this proceeding to the current owner(s). An attorney or agent receiving this communication who does not represent the current owner(s) may wish to seek to withdraw pursuant to 37 CFR 1.36 in order to avoid receiving future communications. If the address of the current owner(s) is unknown, this communication should be returned within the request to withdraw pursuant to Section 1.36.

cc: Third Party Requester(if any)
ABBOTT DIABETES CARE INC.
BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVE., SUITE 200
EAST PALO ALTO, CA 94303

/sdstevenson/

Legal Instruments Examiner
Central Reexamination Unit 571-272-7705; FAX No. 571-273-9900

PTO/SB/57 (02-09)
Approved for use through 02/28/2013. OMB 0651-0064
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

(Also referred to as FORM PTO-1465)

REQUEST FOR *EX PARTE* REEXAMINATION TRANSMITTAL FORM

Address to:
Mail Stop *Ex Parte* Reexam
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attorney Docket No.: ADCI-GEN55

Date: March 31, 2011

1. ☒ This is a request for *ex parte* reexamination pursuant to 37 CFR 1.510 of patent number 7,899,511 issued March 1, 2011. The request is made by:
   ☐ patent owner. ☒ third party requester.

2. ☒ The name and address of the person requesting reexamination is:
   Abbott Diabetes Care Inc.
   Bozicevic, Field & Francis, LLP
   1900 University Avenue, Suite 200, East Palo Alto, CA

3. ☐ a. A check in the amount of $_____ is enclosed to cover the reexamination fee, 37 CFR 1.20(c)(1);
   ☒ b. The Director is hereby authorized to charge the fee as set forth in 37 CFR 1.20(c)(1) to Deposit Account No. 50-0815 ; **or**
   ☒ c. Payment by credit card. Form PTO-2038 is attached.

4. ☒ Any refund should be made by ☐ check or ☒ credit to Deposit Account No. 50-0815 37 CFR 1.26(c). If payment is made by credit card, refund must be to credit card account.

5. ☒ A copy of the patent to be reexamined having a double column format on one side of a separate paper is enclosed. 37 CFR 1.510(b)(4)

6. ☐ CD-ROM or CD-R in duplicate, Computer Program (Appendix) or large table
   ☐ Landscape Table on CD

7. ☐ Nucleotide and/or Amino Acid Sequence Submission
   If applicable, items a. – c. are required.
   a. ☐ Computer Readable Form (CRF)
   b. Specification Sequence Listing on:
      i. ☐ CD-ROM (2 copies) or CD-R (2 copies); **or**
      ii. ☐ paper
   c. ☐ Statements verifying identity of above copies

8. ☒ A copy of any disclaimer, certificate of correction or reexamination certificate issued in the patent is included.

9. ☒ Reexamination of claim(s) 1-41 is requested.

10. ☒ A copy of every patent or printed publication relied upon is submitted herewith including a listing thereof on Form PTO/SB/08, PTO-1449, or equivalent.

11. ☐ An English language translation of all necessary and pertinent non-English language patents and/or printed publications is included.

12. ☒ The attached detailed request includes at least the following items:

a. A statement identifying each substantial new question of patentability based on prior patents and printed publications. 37 CFR 1.510(b)(1)
b. An identification of every claim for which reexamination is requested, and a detailed explanation of the pertinency and manner of applying the cited art to every claim for which reexamination is requested. 37 CFR 1.510(b)(2).

13. ☐ A proposed amendment is included (only where the patent owner is the requester). 37 CFR 1.510(e)

14. ☒ a. It is certified that a copy of this request (if filed by other than the patent owner) has been served in its entirety on the patent owner as provided in 37 CFR 1.33(c).
The name and address of the party served and the date of service are:

Knobbe Martens Olson & Bear LLP

2040 Main Street, Fourteenth Floor

Irvine, CA 92614

Date of Service: March 31, 2011; **or**

☐ b. A duplicate copy is enclosed because service on patent owner was not possible. An explanation of the efforts made to serve patent owner **is attached**. See MPEP 2220.

15. Correspondence Address: Direct all communications about the reexamination to:

☒ The address associated with Customer Number: 85783

OR

☐ Firm or Individual Name

Address

Bozicevic, Field & Francis, LLP, 1900 University Avenue, Suite 200

City East Palo Alto	State CA	Zip 94303
Country US		
Telephone 650-327-3400	Email docket@bozpat.com	

16. ☐ The patent is currently the subject of the following concurrent proceeding(s):

☐ a. Copending reissue Application No. _____

☐ b. Copending reexamination Control No. _____

☐ c. Copending Interference No. _____

☐ d. Copending litigation styled:

_____

_____

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

/Edward J. Baba, Reg. No. 52,581/ — Authorized Signature

3/31/2011 — Date

Edward J. Baba — Typed/Printed Name

52,581 — Registration No.

☐ For Patent Owner Requester

☒ For Third Party Requester

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of: Shults et al.	Attorney Docket No. ADCI-GEN55
U.S. Patent No.: 7,899,511 (*issued from Appl. No. 11/333,837*)	Group Art Unit: *Not yet assigned*
Issued: March 1, 2011	Confirmation No. *Not yet assigned*
For: Low Oxygen In Vivo Analyte Sensor	Examiner: *Not yet assigned*
	Reexamination Control No.: *Not yet assigned*

ABBOTT DIABETES CARE INC.'S
REQUEST FOR *EX PARTE* REEXAMINATION
OF U.S. PATENT NO. 7,899,511
UNDER 35 U.S.C. § 302 AND 37 C.F.R. § 1.510

Mail Stop *Ex Parte* Reexam
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Abbott Diabetes Care Inc. (hereinafter "Requestor") requests reexamination under 35 U.S.C. § 302 and 37 C.F.R. § 1.510 of U.S. Patent No. 7,899,511, which issued on March 1, 2011, to Shults et al. (hereinafter "the Shults '511 patent").

As is fully explained and supported below, a substantial new question of patentability of claims 1-41 of the Shults '511 patent is raised by prior art teachings that were not considered or applied by the examiner during the original prosecution of the Shults '511 patent. More specifically, as outlined in Section V, a substantial new question of patentability is raised by teachings in each of the Rhodes '874 publication, the Kusano publication, the Kerner publication, the Jung '472 publication, and the Sternberg publication, alone or in combination. As such, a reasonable examiner would have considered the teachings of the Rhodes '874 publication, the Kusano publication, the Kerner publication, the Jung '472 publication, and the Sternberg publication, alone or in combination, to be important in deciding whether the recited claims are patentable.

Pursuant to 37 C.F.R. § 1.510, included with this request for *ex parte* reexamination are the following:

- a citation of the publications that are presented to provide substantial new questions of patentability (37 C.F.R. § 1.501);
- the fee for requesting *ex parte* reexamination as set forth in 37 C.F.R. § 1.20(c)(1) (paid via EFS Fee Payment Screen) (37 C.F.R. § 1.510(a));
- a statement pointing out each substantial new question of patentability based on the cited publications (37 C.F.R. § 1.510(b)(1));
- an identification of every claim for which reexamination is requested, and a detailed explanation of the manner and pertinence of applying the publications to every claim for which reexamination is requested (37 C.F.R. § 1.510(b)(2));
- a copy of each publications relied upon or referred to in this request (37 C.F.R. § 1.510(b)(3));
- a copy of the entire patent (in double column format) for which reexamination is requested, and a copy of any disclaimer, certificate of correction, or reexamination certificate issued in the patent (37 C.F.R. § 1.510(b)(4));
- a certification that this request has been served in its entirety on the patent owner through the attorney of record during prosecution (37 C.F.R. § 1.510(b)(5)); and
- a statement that the attorney filing this request has the authority to act on behalf of the Requestor pursuant to 37 C.F.R. § 1.34 (37 C.F.R. § 1.510(f)).

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I. IDENTIFICATION OF CLAIMS FOR WHICH REEXAMINATION IS REQUESTED (37 C.F.R. § 1.510(b)(2))

Ex parte reexamination is requested of claims 1-41 of the Shults '511 patent. Claims 1-41 of the Shults '511 patent are hereinafter referred to individually and/or collectively as "the claims for which reexamination is requested." In accordance with 37 C.F.R. § 1.510(b)(4), a copy of the Shults '511 patent is attached as **Exhibit A**.

II. CITATION OF PRIOR ART (37 C.F.R. § 1.501)

Reexamination is requested in view of the following documents, which are listed on the accompanying Form PTO/SB/08A. In accordance with 37 C.F.R. § 1.510(b)(3), a copy of each of the following references is attached.

Exhibit	Prior Art Document	Previously Cited?	Applied By The Examiner During Prosecution?
B	U.S. Patent Application Publication No. 2003/0032874 (herein referred to as "the Rhodes '874 publication").	**Yes**	**No**
C	Kusano, H., Glucose enzyme electrode with percutaneous interface which operates independently of dissolved oxygen, *Clin. Phys. Physiol. Meas.*, vol. 10, 1:1-9 (1989) (herein referred to as "the Kusano publication").	**No**	**No**
D	Kerner, *et al.*, A Potentially Implantable Enzyme Electrode for Amperometric Measurement of Glucose, *Horm Metab Res Suppl.*, 20:8-13 (1989) (herein referred to as "the Kerner publication").	**Yes**	**Yes**
E	U.S. Patent Application Publication No. 2004/0173472 (herein referred to as "the Jung '472 publication").	**Yes**	**Yes**
F	Sternberg, *et al.*, Covalent Enzyme Coupling on Cellulose Acetate Membranes for Glucose Sensor Development, *Anal. Chem.*, 60: 2781-2786 (1988) (herein referred to as "the Sternberg publication").	**No**	**No**

The Rhodes '874 publication published on February 13, 2003, which is more than one year before the effective filing date of the Shults '511 patent. As such, the Rhodes '874 publication qualifies as prior art under 35 U.S.C. § 102(b).

The Kusano publication published in 1989, which is more than one year before the effective filing date of the Shults '511 patent. As such, the Kusano publication qualifies as prior art under 35 U.S.C. § 102(b).

The Kerner publication published in 1988, which is more than one year before the effective filing date of the Shults '511 patent. As such, the Kerner publication qualifies as prior art under 35 U.S.C. § 102(b).

The Jung '472 publication was filed on September 28, 2001, which is before the effective filing date of the Shults '511 patent. As such, the Jung '472 publication qualifies as prior art under 35 U.S.C. § 102(e).

The Sternberg publication published in 1988, which is more than one year before the effective filing date of the Shults '511 patent. As such, the Sternberg publication qualifies as prior art under 35 U.S.C. § 102(b).

III. OVERVIEW OF APPLICABLE PATENT LAW

A. Substantial New Question of Patentability

In determining whether a substantial new question of patentability (SNQ) exists, M.P.E.P. § 2242, Subtitle I, paragraph 3, provides:

> A prior art patent or printed publication raises a substantial new question of patentability where there is a substantial likelihood that a reasonable examiner would consider the prior art or printed publication important in deciding whether or not the claim is patentable.

The Federal Circuit has held that "the existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office." *In re Swanson*, 540 F.3d 1368,1379-1380 (Fed. Cir. 2008). Thus, "a reference may present a substantial new question even if the examiner considered or cited a reference for one purpose in earlier proceedings." *Id.* The M.P.E.P. is consistent with the *Swanson* decision. M.P.E.P. § 2258.01(A) provides that "[f]or a reexamination that was ordered on or after November 2, 2002 ... reliance solely on old art (as the basis for a rejection) does not necessarily preclude the existence of a substantial new question of patentability that is based exclusively on that old art." Thus, "a SNQ may be based solely on old art where the old art is being presented/viewed in a new light, or in a different way, as compared with its use in the earlier concluded examination(s)." *Id.*

B. Broadest Reasonable Construction

For purposes of this reexamination request, each term of the claims is to be given its "broadest reasonable construction" consistent with the specification. M.P.E.P. § 2111; *In re Trans Texas Holding Corp.*, 498 F.3d 1290, 1298 (Fed. Cir. 2007). As the Federal Circuit noted in *Trans Texas*, the USPTO has traditionally applied this standard during reexamination and does not interpret claims as a court would interpret claims. Rather:

> [T]he PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification.

In re Morris, 127 F.3d 1048, 1054-55 (Fed. Cir. 1997).

The rationale underlying the "broadest reasonable construction" standard is that it reduces the possibility that a claim, after issuance or certificate of reexamination, will be interpreted more broadly than is justified. 37 C.F.R. § 1.555(b); M.P.E.P. § 2111.

C. Overview of Anticipation

A patent is unpatentable under 35 U.S.C. § 102 if it is anticipated by a prior art reference. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). A feature may be inherent if "the prior art necessarily functions in accordance with, or includes, the limitations." *Telemac Cellular Corp. v. Top Telecom, Inc.*, 247 F.3d 1316, 1328 (Fed. Cir. 2001). While normally only one reference should be used in making a rejection under 35 U.S.C. § 102, multiple references may be used when an extra reference is cited to show that a characteristic, which may not be disclosed in the main reference, is inherent. M.P.E.P. § 2131.01. The critical date of the extra reference, which is being used solely to show a universal fact, need not antedate the filing date of the application in question. *Id.*

D. Overview of Obviousness

Section 103 forbids issuance of a patent when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). In making an obviousness determination, "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions." *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007). In *KSR*, the Supreme Court rejected the "rigid approach" of the former "teaching-suggestion-motivation to combine" or "TSM" test. *Id.* at 1739. At the same time, the Court reaffirmed the principles of obviousness set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). *Id.* at 1734.

The obviousness analysis involves the comparison of the broadly construed claim to the prior art. In comparing the claim to the prior art, three factual inquiries must be addressed: (1)

the scope and content of the prior art must be ascertained; (2) the differences between the claimed invention and the prior art must be determined; and (3) the level of ordinary skill in the pertinent art at the time the invention was made must be evaluated. *Graham*, 383 U.S. at 17-18. As stated by the Supreme Court in *KSR*, "[w]hile the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls." *KSR*, 127 S.Ct. at 1734.

In view of the Supreme Court's decision in *KSR*, the Office issued "Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*" See 72 Fed. Reg. 57,526 (Oct. 10, 2007) (hereinafter "Examination Guidelines"). According to the Examination Guidelines, "the Supreme Court particularly emphasized 'the need for caution in granting a patent based on the combination of elements found in the prior art.'" 72 Fed. Reg. at 57,526 (citing to *KSR*). The guidelines further state that "the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge." 72 Fed. Reg. at 57,527. According to the Supreme Court, the "person of ordinary skill" should be viewed as "a person of ordinary creativity, not an automaton." *KSR*, 127 S.Ct. at 1742. The Supreme Court further stated that "in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id.*

Further, "[w]here a claimed range overlaps with a range disclosed in the prior art, there is a presumption of obviousness." *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006) (citations omitted); see also M.P.E.P. § 2144.05.

IV. OVERVIEW OF THE SHULTS '511 PATENT

A. The Shults '511 patent

The Shults '511 patent issued on March 1, 2011, from U.S. Patent Application No. 11/333,837 ("the Shults '837 application"). The Shults '837 application was filed on January 17, 2006, and claims priority as a continuation-in-part of U.S. Application Ser. No. 11/077,714, filed Mar. 10, 2005; which claims priority under 35 U.S.C. 119(e) to U.S. Provisional Application No. 60/614,683, filed Sep. 30, 2004; U.S. Provisional Application No. 60/614,764, filed Sep. 30, 2004; U.S. Provisional Application No. 60/587,787, filed Jul. 13, 2004; and U.S. Provisional Application No. 60/587,800, filed Jul. 13, 2004.

The Shults '511 patent relates to devices for measuring glucose levels in a host. See the Shults '511 patent, col. 1, lns. 17-21. More specifically, the Shults '511 patent claims a glucose sensor system having an electrode and a membrane disposed over the electrode. See, for example, claims 1-41; and col. 1, lns. 55-67. The membrane is configured to limit transport of glucose to the electrode. *Id.* The system also includes an enzyme to catalyze a reaction of glucose and oxygen. *Id.*

Most relevant to this reexamination request, the system claimed in the Shults '511 patent is configured to have "a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL." See claims 1-27. Additionally, the system claimed in the Shults '511 patent is "configured to accurately measure glucose concentration of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L." See claims 28-41. As will be outlined below, such features played an important role in the examiner's decision to allow the claims for which reexamination is requested.

B. Issued Claims of the Shults '511 patent

The Shults '511 patent issued with three independent claims (1, 12, and 28), and 41 total claims. A complete listing of the claims for which reexamination is requested is provided in **Exhibit G**. For convenience, claims 1, 3, 9, 10, 12, 17-20, 22, 25, -26, 28, 30-32, 34, and 40 are reproduced below with emphasis provided on the key limitations that are discussed in more detail below.

1. A glucose sensor system comprising:

an electrode configured to measure a concentration of glucose in a host, wherein the electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2;

a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and

sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode, wherein the sensor electronics are configured to measure the current flow in at least a picoAmp range;

wherein the system is ***configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL***, and wherein the system is configured to measure the current flow associated with the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L.

3. The glucose sensor system of claim 1, further comprising ***an analog-to-digital converter configured to translate the current flow measurement to a digital signal***.

9. The glucose sensor system of claim 1, wherein the system is ***configured to measure glucose with substantial linearity at an oxygen concentration of less than about 0.3mg/L***.

10. The glucose sensor system of claim 1, wherein the system is ***configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation***.

12. A glucose sensor system comprising:

an electrode configured to measure a concentration of glucose in a host;

a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and

sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode;

wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L, and wherein the

system is ***configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL***.

17. The glucose sensor system of claim 12, ***wherein the glucose sensitivity is from about 1 pA/mg/dL to about 10 pA/mg/dL***.

18. The glucose sensor system of claim 12, wherein the system is ***configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.15 mg/L***.

19. The glucose sensor system of claim 12, wherein the system ***is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.05 mg/L***.

20. The glucose sensor system of claim 12, wherein the system ***is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.02 mg/L***.

22. The glucose sensor system of claim 12, further comprising ***an analog-to-digital converter configured to translate the current flow measurement to a digital signal***.

25. The glucose sensor system of claim 12, wherein the system is configured to measure glucose ***with substantial linearity at an oxygen concentration of less than about 0.3mg/L***.

26. The glucose sensor system of claim 12, wherein the system is ***configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation***.

28. A glucose sensor system comprising:

an electrode configured to measure a concentration of glucose in a host;

a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and

sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode;

wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL, and wherein the system is ***configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L***.

30. The glucose sensor system of claim 28, wherein the system is configured to accurately ***measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.15 mg/L***.

31. The glucose sensor system of claim 28, wherein the system is configured to accurately ***measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.05 mg/L***.

32. The glucose sensor system of claim 28, wherein the system is configured to accurately ***measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.02 mg/L***.

34. The glucose sensor system of claim 28, further comprising ***an analog-to-digital converter configured to translate the current flow measurement to a digital signal***.

40. The glucose sensor system of claim 28, wherein the system is ***configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation***.

C. Relevant Prosecution History of the Shults '511 patent

The Shults '837 application was filed with 28 original claims. On November 5, 2007, a Preliminary Amendment was filed, cancelling claims 1-28 and adding claims 29-56. On April 30, 2008, another Preliminary Amendment was filed, cancelling claims 29-56 and adding claims 57-61. Independent application claim 57, which was the only independent claim originally considered by the examiner, is reproduced below.

> 57. A transcutaneous analyte sensor system comprising:
>
> an electrode configured to measure a level of glucose in a host;
>
> a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and
>
> a sensor electronics operably connected to the electrode and configured to measure a current flow in at least a picoAmp range, wherein the system is configured to have a glucose sensitivity of from about 5 pA/mg/dL to about 25 pA/mg/dL, wherein the electrode comprises an exposed electroactive working electrode with a surface area between about 0.000084 cm^2 to about 0.016 cm^2, and wherein the system is configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L.

On November 28, 2008, the examiner issued a first office action on the merits. In relevant part, claim 57 was rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,165,407 ("the Wilson '407 patent") in view of U.S. Patent No. 6,893,552 ("the Wang '552 patent"). The examiner determined that the Wilson '407 patent taught each feature of the claims, except that the Wilson '407 patent taught a sensitivity of about 32.7 pA/mg/dL and did not explicitly teach the oxygen concentration of the fluid. With regard to the claimed limitation of a sensitivity from about 5 pA/mg/dL to about 25 pA/mg/dL, the examiner concluded that the Wilson '407 patent taught a sensitivity of about 32.7 pA/mg/dL, which was equivalent to about 25 pA/mg/dL. See Office Action, dated Nov. 28, 2008, pg. 2. With regard to the claimed limitation of the oxygen concentration of the fluid being less than about 0.6 mg/L, the examiner concluded that the Wang '552 patent taught the measurement of current with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L. *Id.* at pgs. 3-4. The examiner then concluded that it would be obvious to combine the teachings of the Wilson '407 patent with the teachings of the Wang '552 patent to meet the claimed analyte sensor system. *Id.* at pg. 4.

On January 13, 2009, the applicants interviewed the case with the examiner. The Interview Summary indicated that the examiner and the applicants' representative discussed and agreed that the prior art references were not combinable.

In a response filed on February 25, 2009, the applicants argued that the cited prior art references were not combinable at least in part because the Wang '552 patent taught a sensor configured to operate with a fluorocarbon binder polychlorotrifluorethylene (Kei-F) fulfilling the role of oxygen. Thus, the applicants argued that the Wang '552 patent was not combinable with the Wilson '407 patent because the Wang '552 patent explicitly taught the lack of a diffusion limiting membrane. The applicants further argued:

> Simply put, the Wilson sensor modified with Wang's teachings (e.g., by eliminating a diffusion limiting membrane) ***cannot be presumed to still be capable of having a sensitivity between about 5 and 25 pA/mg/dL***. Conversely, the Wang sensor modified with Wilson's teachings (e.g., by incorporating a diffusion limiting membrane) ***cannot be presumed to still be capable of having substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L***. Thus, without specific guidance in Wilson or Wang that would provide a skilled person with sufficient direction to construct a device capable of achieving both aforementioned features, the Examiner's hypothetically constructed devices cannot be presumed to arrive at the invention recited in Claim 57.

Response filed Feb. 25, 2009, pg. 9 (emphasis added).

The applicants also amended claims 57-61 and added claims 62-74. Relevant to this reexamination request, amended claim 57, and newly added claims 63, and 71-74, are presented below:

> 57. (*Amended*) An ~~transcutaneous~~ analyte sensor system comprising:
>
> an electrode configured to measure a level of glucose in a host;
>
> a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and
>
> a sensor electronics operably connected to the electrode and configured to measure a current flow in at least a picoAmp range, wherein the system is configured to have a glucose sensitivity of from about [[5]] 1 pA/mg/dL to about 25 pA/mg/dL, wherein the electrode comprises an exposed electroactive working electrode with a surface area between about 0.000084 cm^2 to about 0.016 cm^2, and wherein the system is configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L.

63. (*New*) An analyte sensor system comprising:

an electrode configured to measure a level of glucose in a host;

a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and

sensor electronics operably connected to the electrode and configured to measure a current flow produced by the electrode, wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL, and wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L.

71. (*New*) The analyte sensor system of Claim 63, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L.

72. (*New*) The analyte sensor system of Claim 63, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.15 mg/L.

73. (*New*) The analyte sensor system of Claim 63, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.05 mg/L.

74. (*New*) The analyte sensor system of Claim 63, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.02 mg/L.

On June 29, 2009, the examiner issued another non-final office action. In relevant part, the following prior art rejections were presented:

1) Claims 57, 58, 63-65, and 69-74 were rejected under 35 U.S.C. §§ 102(b)/103(a) as being anticipated by or, in the alternative, being unpatentable over the Wilson '407 patent.

> 2) Claims 57, 58, 60-62, and 64 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Shults '067 patent in view of the Wilson '407 patent.
>
> 3) Claims 63 and 65-74 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Shults '067 patent.

Claims 57 and 63 were the only independent claims.

With regard to the Wilson '407 patent, the examiner argued that the Wilson '407 patent taught all the features of the claims, except that the Wilson '407 patent taught a glucose sensitivity of 32.7 pA/mg/dL (which the examiner equated to "about 25 pA/mg/dL") and that the Wilson '407 patent was silent as to the oxygen concentration of the fluid. The examiner, however, concluded:

> because the structure of the system of [the Wilson '407 patent] is substantially identical to that recited in claims 57, 63, and 64, it is assumed that the systems, therefore, inherently have the same properties or functions, such that is [sic] assumed that [the Wilson '407 patent] inherently exhibits the recited sensitivities of [sic] and/or linearity in the recited oxygen concentrations.

Office Action dated June 29, 2009, pgs. 4-5.

With regard to the use of the Shults '067 patent, the examiner argued:

> The system [of the Shults '067 patent] is configure to have a glucose sensitivity of ***from about 1 to 100 pA/mg/dL*** and the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL ***in a fluid with an oxygen concentration of about 0.8 mg/dL*** (see entire document, especially fig. 4; col. 21, lines 1-24 of Shults) ***rather than "less than about 0.6 mg/dL"*** (or any of the ranges recited in claims 71-74). However, when the claimed range and the prior art range are very [sic] the range of the prior art establishes prima facie obviousness because one of ordinary skill in the art would have expected the similar ranges to have the same properties. *See in re Peterson*, 65 USPQ2d 1379, 1382, citing *titanium* [sic] *Metals Corp. V. Banner*, 227 USPQ 773, 779.

Office Action dated June 29, 2009, pg. 9 (emphasis added).

In a response filed on November 23, 2009, the applicants presented arguments over the prior art without substantively amending any of the claims.[1] The applicants argued two key

[1] The duplicated claims 65 were cancelled and re-presented as claims 75 and 76, respectively.

allegedly patentable features to the claims: (1) the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L; and (2) a sensitivity range from about 1 pA/mg/dL to 25 pA/mg/dL.

With regard to the claimed limitation of measuring glucose at oxygen concentrations of less than about 0.6 mg/L, the applicants argued that the Wilson '407 patent and the Shults '067 patent failed to disclose the claimed feature. First, the applicants argued that the Wilson '407 patent was silent with regard to the oxygen concentration and that the examiner's assumption that the Wilson '407 patent inherently met the claimed feature was flawed. See Response filed Nov. 23, 2009, pgs. 8-9. Next, the applicants argued that the Shults '067 patent taught an oxygen concentration down to 0.8 mg/L, but would have significant inaccuracies at oxygen concentrations less than about 0.6 mg/L. *See Id.* at pgs. 15-16.

With regard to the claimed sensitivity range, the applicants argued that the Wilson '407 patent taught a sensitivity range of about 34.85 pA/mg/dL to 90.61 pA/mg/dL, which does not overlap with the claimed range of about 1 pA/mg/dL to 25 pA/mg/dL. *See Id.* at pgs. 9-10. The applicants then argued that "it cannot be presumed that, after modification of the Shults working electrode to have the particular exposed surface area described in [the Wilson '407 patent], the Shults sensor would still have a sensitivity within the claimed ranges." *Id.* at pgs. 13-14.

On April 12, 2010, the examiner issued another non-final rejection. Claims 63, 64, 66-69, 71, 75, and 76 were rejected. Claims 57-62 were allowed, and claims 70 and 72-74 were objected to for being dependent on a rejected base claim. In sum, the examiner found new art (i.e., the Kerner publication) that taught accurate glucose measurements at oxygen concentrations down to 0.6 mg/dL. The examiner, however, did not find art that taught: (1) accurate glucose measurements at oxygen concentrations below 0.3 mg/dL; or (2) a sensitivity range from about 1 pA/mg/dL to 25 pA/mg/dL.

In relevant part, the examiner rejected claims 63, 64, 68, and 75 under 35 U.S.C. § 102(b) as being anticipated by Kerner, *et al.*, A Potentially Implantable Enzyme Electrode for Amperometric Measurement of Glucose, *Horm Metab Res Suppl.*, 20:8-13 (1989) ("the Kerner publication"). The examiner held that the Kerner publication taught each and every limitation of the claims. Specifically, the examiner concluded:

> The system [of the Kerner publication] ***is configured to have a glucose sensitivity between about 1 and about 100 pA/mg/dL*** (see entire document, especially fig. 1; and "In vivo experiments" section on p. 11 of Kerner), wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL ***in a fluid with an oxygen concentration of less than about 0.6 mg/dL*** (see entire document, especially summary; figs. 4, 5; left hand column on p. 11 of Kerner).

Office Action, dated Apr. 12, 2010, pgs. 2-3 (emphasis added).

The examiner also rejected claim 76 under 35 U.S.C. § 103(a) as being unpatentable over the Kerner publication in view of the Jung publication. The examiner stated that "Kerner lacks an analog-to-digital converter. However, Jung teaches sensors electronics including an analog-to-digital converter configured to translate the current flow measurement to a digital signal…." *Id.* at pgs. 4-5.

With respect to claims 57-62, 69, and 70-74, the examiner stated that the primary reasons for allowance:

> is the inclusion of the ***glucose sensitivity being from about 1 pA/mg/dL to about 10 or about 25 pA/mg/dL***, in combination with all of the other claimed limitations, which is not taught or fairly suggested by the prior art of record.
>
> Regarding claims 71-74, the primary reason for allowance is the inclusion of the system being configured to accurately measure glucose concentrations of up to about 400 mg/dL ***in a fluid with an oxygen concentration of less than about 0.3, 0.15, 0.05, or 0.02 mg/L***, in combination with all of the other claimed limitations, which is not taught or fairly suggested by the prior art of record.

Office Action, dated Apr. 12, 2010, pg. 8 (emphasis added).

On April 22, 2010, the applicants cancelled claim 63; amended claims 64, 66, 68, and 69-76, 2-11; and added new claims 77-85. Relevant to this reexamination request, application claims 69 and 71 were rewritten in independent form as follows:

> 69. (*Amended*) ~~The analyte sensor system of Claim 63,~~ An analyte sensor system comprising:
>
> an electrode configured to measure a level of glucose in a host;
>
> a membrane disposed over the electrode and configured to limit the transport of glucose to the electrode; and

sensor electronics operably connected to the electrode and configured to measure a current flow produced by the electrode, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L, and wherein the glucose sensitivity is from about 1 pA/mg/dL to about 25 pA/mg/dL.

71. (*Amended*) ~~The analyte sensor system of Claim 63,~~ An analyte sensor system comprising:

an electrode configured to measure a level of glucose in a host;

a membrane disposed over the electrode and configured to limit the transport of glucose to the electrode; and

sensor electronics operably connected to the electrode and configured to measure a current flow produced by the electrode, wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL, and wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L.

The applicants also filed a Terminal Disclaimer to overcome rejections under the doctrine of obviousness-type double patenting. The Terminal Disclaimer, however, was rejected as improper because it was signed by a person who did not have proper power of attorney. Because the Terminal Disclaimer was rejected, on July 2, 2010, the examiner issued a final office action reiterating the rejection of claims 66, 69, and 71 under obviousness-type double patenting over claims 9, 10, 21, and 23 of co-pending U.S. Patent Application No. 12/113,508.

On July 23, 2010, the applicants re-filed the Terminal Disclaimer, with evidence of proper power of attorney, and filed an Amendment After Final. The claims 57, 58, 64, 69, 71, 75, 77, and 81 were amended. Claims 86-99 were added. Relevant to this reexamination request, amendments to independent claims 57, 69, and 71 are provided below.

57. (*Amended*) An analyte sensor system comprising:

an electrode configured to measure a level of glucose in a host, wherein the electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2;

a membrane disposed over the electrode and configured to limit [[the]] transport of glucose to the electrode; and

a sensor electronics operably connected to the electrode and configured to measure a current flow associated with ~~produced by~~ the electrode, wherein the sensor electronics are configured to measure the current flow in at least a picoAmp range;

wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL, ~~wherein the electrode comprises an exposed electroactive working electrode with a surface area between about 0.000084 cm^2 to about 0.016 cm^2,~~ and wherein the system is configured to measure a current associated with ~~produced by~~ the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L.

69. (*Amended*) An analyte sensor system comprising:

an electrode configured to measure a level of glucose in a host;

a membrane disposed over the electrode and configured to limit [[the]] transport of glucose to the electrode; and

sensor electronics operably connected to the electrode and configured to measure a current flow associated with ~~produced by~~ the electrode[[,]];

wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L, and wherein the system is configured to have a glucose sensitivity [[is]] of from about 1 pA/mg/dL to about 25 pA/mg/dL.

70. (*Previously Presented*) The analyte sensor system of Claim 69, wherein the glucose sensitivity is from about 1 pA/mg/dL to about 10 pA/mg/dL.

71. (*Amended*) An analyte sensor system comprising:

an electrode configured to measure a level of glucose in a host;

a membrane disposed over the electrode and configured to limit [[the]] transport of glucose to the electrode; and

sensor electronics operably connected to the electrode and configured to measure a current flow associated with ~~produced by~~ the electrode[[,]];

> wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL, and wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L.

On August 11, 2010, the examiner issued a Notice of Allowance. On March 1, 2011, the Shults '837 application issued as the Shults '511 patent. Independent application claims 57, 69, and 71 were renumbered and issued as independent patent claims 1, 12, and 28, respectively. For convenience, a table summarizing the renumbering of the application claims is provided as **Exhibit H**.

V. STATEMENT POINTING OUT EACH SUBSTANTIAL NEW QUESTION OF PATENTABILITY (37 C.F.R. § 1.510(b)(1))

A. General Statement of Patentability

The considerations that led to the examiner's allowance of issued claims 1, 12, and 28 (application claims 57, 69, and 71, respectively) are important. During the original prosecution of the Shults '511 patent, a critical issue was whether the prior art taught a sensor system that is "configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL." Such feature was argued by the applicants to distinguish claims 1 and 12 (and dependents thereof) over the prior art. A second critical issue was whether the prior art taught a sensor system "configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L." Such feature was argued by the applicants to distinguish claim 28 (and dependents thereof) over the prior art.

In the Office Action dated April 12, 2010, the Examiner emphasized the following reasons for allowance of the pending claims:

> Regarding claims 57-62, 69, and 70, the primary reason for allowance is the inclusion of the ***glucose sensitivity being from about 1 pA/mg/dL to about 10 or about 25 pA/mg/dL***, in combination with all of the other claimed limitations, which is not taught or fairly suggested by the prior art of record.
>
> Regarding claims 71-74, the primary reason for allowance is the inclusion of the system being configured to accurately measure glucose concentrations of up to about 400 mg/dL ***in a fluid with an oxygen concentration of less than about 0.3, 0.15, 0.05, or 0.02 mg/L***, in combination with all of the other claimed limitations, which is not taught or fairly suggested by the prior art of record.

(Emphasis added.)

As such, the examiner considered the patentable features to be a sensor system configured to: (1) have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL; and (2) measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L. As outlined below, such features are taught by the unconsidered prior art teachings of the Rhodes '874 publication and the Kusano publication.

B. The Rhodes '874 publication raises an SNQ because the Rhodes '874 publication teaches a sensor system configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL.

The Rhodes '874 publication was cited during prosecution of the Shults '511 patent, but the teachings of the Rhodes '874 publication were not applied against the claims of the Shults '511 patent.

The Rhodes '874 publication teaches a glucose sensor system that is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL, as called for in claims 1-27 of the Shults '511 patent. There is no indication that the examiner found, considered, or applied any prior art reference that taught such limitation. In fact, the examiner explicitly stated that claim 1 (application claim 57) was allowable because of the "inclusion of the glucose sensitivity being from about 1 pA/mg/dL to about 10 or about 25 pA/mg/dL." See Office Action, dated Apr. 12, 2010, pg. 8. As such, a reasonable examiner would consider the teachings of the Rhodes '874 publication important in deciding whether claims 1-27 are patentable.

The Rhodes '874 publication is directed to the same problem as the Shults '511 patent. Namely, the Rhodes '874 publication is directed to the development of a glucose sensor system to measure glucose concentration in low oxygen environments. See the Rhodes '874 publication, Abstract. More specifically, the Rhodes '874 publication discloses an implantable glucose sensor that showed no oxygen dependence to oxygen concentrations as low as 0.1 mg/L, and a sensitivity of at least 5.5 pA/mg/dL, to increasing concentrations up to 400 mg/dL of glucose. *See Id.* at FIGs. 3 and 9; pgs. 6-7, [0083]-[0085]; and pg. 11, [0131]-[0141]. As such, the disclosed sensor sensitivity of at least 5.5 pA/mg/dL in the Rhodes '874 publication falls within the claimed range of about 1 pA/mg/dL to about 25 pA/mg/dL in the Shults '511 patent.

There is no indication that the examiner applied any prior art references that taught a sensor system with a sensitivity falling within the claimed range of from about 1 pA/mg/dL to about 25 pA/mg/dL. As stated above, the Rhodes '874 publication teaches a sensor system with a sensitivity falling within the claimed range. As such, the Rhodes '874 publication raises a substantial new question of patentability because a reasonable examiner would consider the teachings of the Rhodes '874 publication important in deciding whether claims 1-27 are patentable. See M.P.E.P. § 2242, Subtitle I, paragraph 3.

A detailed explanation of the pertinence and manner of applying the teachings of the Rhodes '874 publication to claims 1-27 is provided below in Section VI.

C. The Rhodes '874 publication raises an SNQ because the Rhodes '874 publication teaches a sensor system configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L.

The Rhodes '874 publication was cited during prosecution of the Shults '511 patent, but the teachings of the Rhodes '874 publication were not applied against the claims of the Shults '511 patent.

The Rhodes '874 publication teaches a glucose sensor system to measure glucose concentration in a fluid with an oxygen concentration of less than about 0.3 mg/L, as called for in claims 9, 18, 28-30, and 33-41 of the Shults '511 patent. There is no indication that the examiner found, considered, or applied any prior art reference that taught such limitation. In fact, the examiner explicitly stated that claim 28 (application claim 71) was allowable because of "the inclusion of the system being configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3, 0.15, 0.05, or 0.02 mg/L." See Office Action, dated Apr. 12, 2010, pg. 8. As such, a reasonable examiner would consider the teachings of the Rhodes '874 publication important in deciding whether the claims 9, 18, 28-30, and 33-41 are patentable.

The Rhodes '874 publication is directed to the same problem as the Shults '511 patent; e.g., the development of a glucose sensor system for measuring glucose concentration in low oxygen environments. See, for example, the Rhodes '874 publication, pg. 1, [0003]; and pg. 2, [0011]. The Rhodes '874 publication states, "there is a need for a sensor that will provide accurate analyte measurements, … and that will function effectively and efficiently in low oxygen concentration environments." *Id.* at pg. 2, [0011].

The Rhodes '874 publication presents a sensor system that address the oxygen deficiency problem and measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.3 mg/L. Specifically, in EXAMPLE 2, on page 10, the Rhodes '874 publication states, "A glucose value was recorded for each device at decreasing oxygen concentrations from ambient to approximately 0.1 mg/L." *Id.* at pg. 10, [0136]. As such, the Rhodes '874

publication shows a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.3 mg/L, as called for in claims 9, 18, 28-31, and 33-41.

There is no indication that the examiner applied any prior art references that taught a sensor system that measures glucose in a fluid with an oxygen concentration of less than about 0.3 mg/L, as called for in claims 9, 18, 28-30, and 33-41 of the Shults '511 patent. As outlined above, such limitation is taught by the Rhodes '874 publication. As such, the Rhodes '874 publication raises a substantial new question of patentability because a reasonable examiner would consider the teachings of the Rhodes '874 publication important in deciding whether claims 9, 18, 28-30, and 33-41 are patentable. See M.P.E.P. § 2242, Subtitle I, paragraph 3.

A detailed explanation of the pertinence and manner of applying the teachings of the Rhodes '874 publication to claims 9, 18, 28-30, and 33-41 is provided below in Section VI.

D. The Kusano publication raises an SNQ because the Kusano publication teaches a sensor system configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L.

The Kusano publication was not cited during prosecution of the Shults '511 patent. Further, the examiner did not identify or apply any prior art that taught a sensor system with the features taught in the Kusano publication. The Kusano publication teaches a glucose sensor system that measures a concentration of glucose in a fluid with an oxygen concentration of less than about 0.3 mg/L, as called for in claims 9, 18-20, 25, and 28-41 of the Shults '511 patent. There is no indication that the examiner found, considered, or applied any prior art reference that taught such limitation. In fact, the examiner explicitly stated that claim 28 (application claim 71) was allowable because of "the inclusion of the system being configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3, 0.15, 0.05, or 0.02 mg/L." See Office Action, dated Apr. 12, 2010, pg. 8. As such, a reasonable examiner would consider the teachings of the Kusano publication important in deciding whether the claims for which reexamination is requested are patentable.

The Kusano publication is directed to the same problem as the Shults '511 patent; e.g., the development of a glucose sensor system for measuring glucose concentration in low oxygen environments. See, for example, the Kusano publication, pg. 2. The Kusano publication states, "The glucose electrode with percutaneous interface described in this paper differs from

[previously described electrodes] using a novel approach to overcome the lack of oxygen in the interstitial fluid." *Id.* In other words, the Kusano publication presents a sensor system that address the oxygen deficiency problem, and thus measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.3 mg/L.

Specifically, the Kusano publication states,

> The electrode has a linear response to glucose concentration at an electrode output current ranging from 0 to 20nA ***even when the oxygen concentration of the glucose solution is zero***. The use of polyurethane as a diffusion barrier to glucose limits the electrode output current at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) to 20 nA. Therefore, the electrode can measure glucose concentrations up to 500 mg dl^{-1} (27.8 mmol l^{-1}) ***with no oxygen*** dissolved in the glucose solution.

The Kusano publication, Abstract (emphasis added).

Figure 8 of the Kusano publication (reproduced below) shows a linear current measurement up to 500 mg/dL, even at 0 kPa of Po_2.

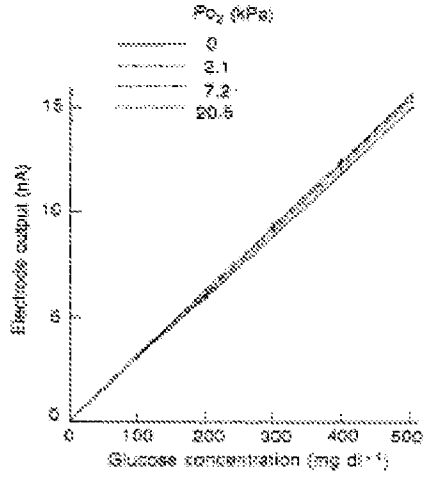


Figure 8. Electrode calibration curves under various Po_2.

The concluding remarks of the Kusano publication further state:

> Glucose concentrations of 0 to 500 mg dl^{-1} (27.8 mmol l^{-1}) could be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (21.7 kPa). Since the electrode is capable of operating where the oxygen concentration is low, it is thought to be suitable for implantation in subcutaneous tissue and may prove to be a key development in the realisation of a closed-loop artificial endocrine pancreas.

The Kusano publication, pg. 8.

There is no indication that the examiner applied any prior art references that taught a glucose sensor system that measures glucose concentration in a fluid with an oxygen concentration of less than about 0.3 mg/L, as called for in claims 9, 18-20, 25, and 28-41 of the Shults '511 patent. As outlined above, such limitation is taught by the Kusano publication. As such, the Kusano publication raises a substantial new question of patentability because a reasonable examiner would consider the teachings of the Kusano publication important in deciding whether claims 9, 18-20, 25, and 28-41 are patentable. See M.P.E.P. § 2242, Subtitle I, paragraph 3.

A detailed explanation of the pertinence and manner of applying the teachings of the Kusano publication to claims 9, 18-20, 25, and 28-41 is provided below in Section VI.

E. The combination of the Kerner publication and the Kusano publication raises an SNQ because the combination teaches a sensor system configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L.

In the office action dated April 12, 2010, the examiner considered and applied the Kerner publication. The examiner, however, acknowledged that the Kerner publication only taught measuring glucose concentrations in a fluid with an oxygen concentration of less than about 0.6 mg/dL. The examiner then concluded that claim 28 (application claim 71) was allowable because of "the inclusion of the system being configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3, 0.15, 0.05, or 0.02 mg/L." See Office Action, dated Apr. 12, 2010, pg. 8. In other words, claim 28 was ultimately allowed because the examiner did not find or apply any prior art that could be combined with the Kerner publication in order to measure glucose concentrations in a fluid with an oxygen concentration of less than about 0.3 mg/L.

The Kusano publication was not cited during prosecution of the Shults '511 patent. Further, the examiner did not identify or apply any prior art that taught a sensor system with the features taught in the Kusano publication. The Kusano publication teaches a simple mechanical modification to a glucose sensor system in order to measure glucose in a fluid with an oxygen concentration of less than about 0.3 mg/L, as called for in claims 28-34, 37, 40, and 41 of the Shults '511 patent. There is no indication that the examiner found, considered, or applied any

prior art reference that taught how to modify a glucose sensor in order to increase its measurement range. In fact, as stated above, the examiner allowed claim 28 (application claim 71) because of "the inclusion of the system being configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3, 0.15, 0.05, or 0.02 mg/L." See Office Action, dated Apr. 12, 2010, pg. 8. As such, a reasonable examiner would consider the teachings of the Kusano publication important in deciding whether the claims for which reexamination is requested are patentable.

The Kusano publication is directed to the same problem as the Kerner publication and the Shults '511 patent; e.g., the development of a glucose sensor system for measuring glucose concentration in low oxygen environments. See, for example, the Kusano publication, pg. 2. The Kusano publication states, "The glucose electrode with percutaneous interface described in this paper differs from [previously described electrodes] using a novel approach to overcome the lack of oxygen in the interstitial fluid." *Id.* In other words, the Kusano publication teaches how to modify a sensor system in order to address the oxygen deficiency problem, and thus measure glucose concentrations in a fluid with an oxygen concentration of less than about 0.3 mg/L.

More specifically, the sensor system of the Kusano publication employs an air intake hole to draw ambient air into the sensor, and thus configures the system to measure glucose concentrations of about 400 mg/dL, even in a fluid with an oxygen concentration at 0 mg/L. See, the Kusano publication, MATERIALS section, pgs. 2-3, and FIG. 2 (reproduced below).

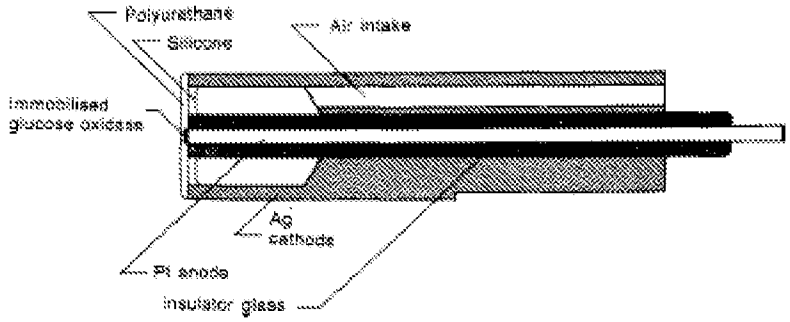


Figure 2. Schematic diagram of the experimental glucose electrode.

The Kusano publication states,

> The electrode has a linear response to glucose concentration at an electrode output current ranging from 0 to 20nA ***even when the oxygen concentration of the glucose solution is zero***. The use of polyurethane as a diffusion barrier to glucose limits the electrode

> output current at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) to 20 nA. Therefore, the electrode can measure glucose concentrations up to 500 mg dl^{-1} (27.8 mmol l^{-1}) ***with no oxygen*** dissolved in the glucose solution.

The Kusano publication, Abstract (emphasis added).

Figure 8 of the Kusano publication (reproduced below) shows a linear current measurement up to 500 mg/dL, even at 0 kPa of Po_2.

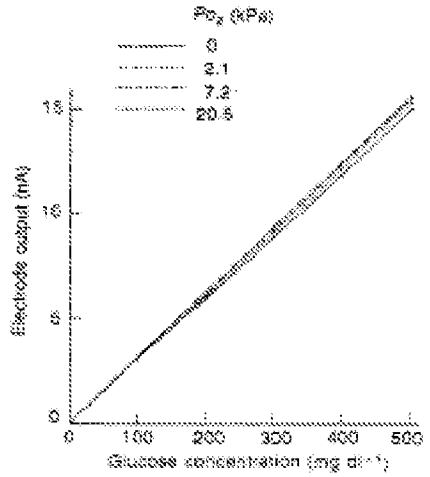


Figure 8. Electrode calibration curves under various Po_2

The concluding remarks of the Kusano publication further state:

> Glucose concentrations of 0 to 500 mg dl^{-1} (27.8 mmol l^{-1}) could be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (21.7 kPa). Since the electrode is capable of operating where the oxygen concentration is low, it is thought to be suitable for implantation in subcutaneous tissue and may prove to be a key development in the realisation of a closed-loop artificial endocrine pancreas.

The Kusano publication, pg. 8.

The air intake hole described in the Kusano publication is a simple mechanical modification to a sensor, which provides ambient oxygen to the electroactive surface. Such modification would be an important consideration for the examiner because one of ordinary skill in the art would understand how to modify the sensor of the Kerner publication to include the air intake hole of the Kusano publication, without undue experimentation and with reasonable expectation of success. For instance, such modification does not change the chemistry, or general function of the sensor of the Kerner publication. Instead, such modification merely

provides ambient oxygen to the sensor when the oxygen concentration within the fluid is inadequate for the function of the sensor. As such, one of ordinary skill in the art would understand how to modify the sensor of the Kerner publication to include the air intake hole of the Kusano publication to measure glucose in a fluid with an oxygen concentration below 0.3 mg/L, as called for in claim 28

There is no indication that the examiner applied any prior art references that taught a glucose sensor system modified to measures glucose concentration in a fluid with an oxygen concentration of less than about 0.3 mg/L, as called for in claims 28-34, 37, 40, and 41 of the Shults '511 patent. As outlined above, such modification is taught by the Kusano publication. As such, the combination of the Kerner publication and the Kusano publication raises a substantial new question of patentability because a reasonable examiner would consider the combination important in deciding whether claims 28-34, 37, 40, and 41 are patentable. See M.P.E.P. § 2242, Subtitle I, paragraph 3.

A detailed explanation of the pertinence and manner of applying the combination of the Kerner publication and the Kusano publication to claims 28-34, 37, 40, and 41 is provided below in Section VI.

F. The use of the Jung publication in combination with the Rhodes '874 publication, the Kerner publication, and/or the Kusano publication, raises an SNQ because the combination teaches a sensor system with an analog-to-digital converter.

In the office action dated April 12, 2010, the examiner considered and applied the Kerner publication in combination with the Jung publication. The examiner stated that "Kerner lacks an analog-to-digital converter. However, Jung teaches sensors electronics including an analog-to-digital converter configured to translate the current flow measurement to a digital signal…." Office Action, dated Apr. 12, 2010, pgs. 4-5.

The examiner, however, acknowledged that the Kerner publication only taught a system configured to have glucose sensitivity between about 1 and about 100 pA/mg/dL, and measuring glucose concentrations in a fluid with an oxygen concentration of less than about 0.6 mg/dL. The examiner ultimately allowed claims 3, 22, and 34, which called for "analog-to-digital converter configured to translate the current flow measurement to a digital signal," because such claims depended from claims calling for a system configured to have glucose sensitivity between

about 1 pA/mg/dL to about 25 pA/mg/dL, and/or measuring glucose concentrations in a fluid with an oxygen concentration of less than about 0.3 mg/L. See Office Action, dated Apr. 12, 2010, pg. 8.

As outlined above, the Rhodes '874 publication, the Kusano publication, and/or the combination of the Kerner publication and the Kusano publication each teach a sensor systems that have glucose sensitivity between about 1 pA/mg/dL to about 25 pA/mg/dL, and/or can measure glucose in a fluid with an oxygen concentration below 0.3 mg/L. As such, an examiner would consider the combination of the Jung publication with any of the Rhodes '874 publication, the Kusano publication, and/or the combination of the Kerner publication and the Kusano publication to be important in deciding whether claims 3, 22, and 34 are patentable.

A detailed explanation of the pertinence and manner of applying the Jung publication to claims 3, 22, and 34 is provided below in Section VI.

G. The Sternberg publication raises an SNQ because the Sternberg publication teaches a sensor system that is configured such that less than about 1μg of enzyme is consumed over 7 days of continuous operation.

The Sternberg publication was not cited during prosecution of the Shults '511 patent. Further, the examiner did not identify or apply any prior art that taught a sensor system with the features taught in the Sternberg publication. The Sternberg publication teaches a sensor system that is configured such that less than about 1μg of enzyme is consumed over 7 days of continuous operation. There is no indication that the examiner found, considered, or applied any prior art reference that taught such feature. Further, such feature, being present in dependent claims 10, 26, and 40, was never discussed during the prosecution of the Shults '511 patent. Because the Sternberg publication teaches the key feature of claims 10, 26, and 40, a reasonable examiner would consider the teachings of the Sternberg publication important in deciding whether claims 10, 26, and 40 are patentable.

The Sternberg publication is directed to the same problem as the Shults '511 patent, which is the development of an implantable sensor system for subcutaneous glucose concentration measurements. See, for example, the Sternberg publication, pg. 2783, Results and Discussion section. The Sternberg publication describes experiments with electrodes containing 3.0 ± 1.2 μg, 6.4 ± 2.2 μg, and 10 ± 1.4 μg of immobilized glucose oxidase (GOx), respectively.

Id. at pg. 2782-83, Table I (procedure "a" provides 3.8 ± 1.5 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 3.0 ± 1.2 μg of enzyme; procedure "b" provides 8.0 ± 2.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 6.4 ± 2.2 μg of enzyme; and procedure "c" provides 13 ± 1.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 10 ± 1.4 μg of enzyme).

As discussed on page 2784 of the Sternberg publication, "Figure 5 compares the time-dependent loss of enzymatic activity with the loss of enzyme mass from the membrane surface." The line noted with the "X" markers in Figure 5 (reproduced below) illustrates the consumption of GOx over about 15 days of continuous use. As shown in Figure 5, the relative consumption of GOx over the first seven days of use is between about 10% and about 15%.

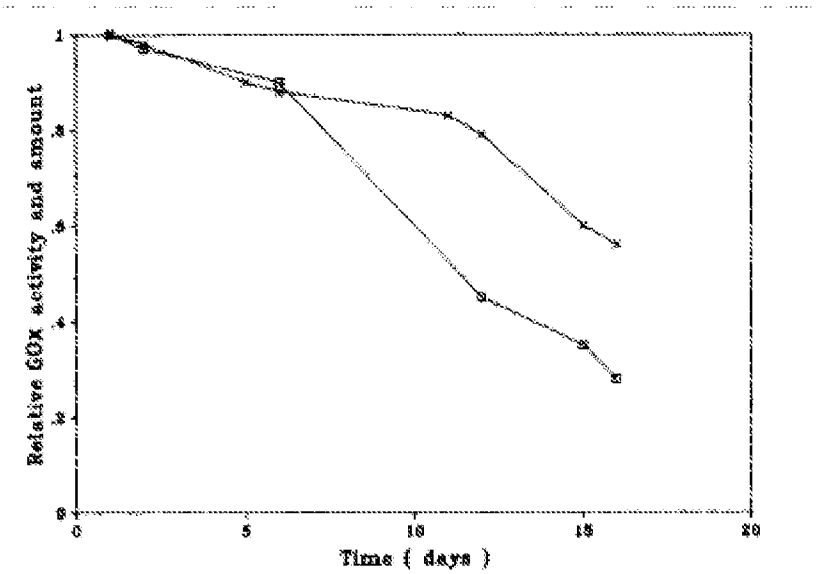


Figure 5. Relative evolution of surface GOx activity (O) and ^{125}I–GOx (X) in a CA–BSA–PBQ–GOx membrane not treated with lysine after coupling.

Considering preparation procedures "a," "b," and "c," which begin with 3.0 ± 1.2 μg; 6.4 ± 2.2 μg; and 10 ± 1.4 μg, respectively, a 10-15% consumption of enzyme would result in consumption of about 0.18-0.63 μg; 0.42-1.3 μg; or 0.86-1.7 μg, respectively. As such, the Sternberg publication teaches a system that is configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation.

The Sternberg publication raises a substantial new question of patentability because it teaches a continuous glucose measurement sensor consuming less than about 1 μg over 7 days of

continuous operation. A reasonable examiner would consider such teachings important in deciding whether claims 10, 26, and 40 are patentable. See M.P.E.P. § 2242, Subtitle I, paragraph 3.

A detailed explanation of the pertinence and manner of applying the teachings of the Sternberg publication to claims 10, 26, and 40 is provided below in Section VI.

VI. DETAILED EXPLANATION OF MANNER AND PERTINENCE OF APPLYING THE CITED PRIOR ART TO EVERY CLAIM FOR WHICH REEXAMINATION IS REQUESTED (37 C.F.R. § 1.510(b)(2))

A. Claims 1, 2, 4-9, 11-18, 21, 23-25, 27-30, 33, 35-39, and 41 are anticipated under 35 U.S.C. § 102 by the Rhodes '874 publication.

Claims 1, 2, 4-9, 11-18, 21, 23-25, 27-30, 33, 35-39, and 41 are anticipated under 35 U.S.C. § 102(b) by the Rhodes '874 publication. Sections VI.A.1 – VI.A.31 detail how claims 1, 2, 4-9, 11-18, 21, 23-25, 27-30, 33, 35-39, and 41 are anticipated under 35 U.S.C. § 102(b) by the Rhodes '874 publication. For the examiner's convenience, the arguments presented below are summarized in the table provided in **Exhibit I**.

1. Independent Claim 1

> Claim 1. A glucose sensor system comprising:
>
> *Part of Claim 1*

The Rhodes '874 publication teaches a glucose sensor system. See the Rhodes '874 publication, Abstract; FIG. 1; and pg. 2, [0012]-[0017].

> an electrode configured to measure a concentration of glucose in a host, wherein the electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2;
>
> *Part of Claim 1*

The Rhodes '874 publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See, for example, the Rhodes '874 publication, Abstract; and pg. 2, [0012]-[0017] and [0020]. The electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2. See, for example, the Rhodes '874 publication, pg. 3, [0022]; and pgs. 8-9, [0110]-[0112]. More specifically, the Rhodes '874 publication describes the use of a wire electrode with a modified reactive surface. *See Id.* at [0112]. The diameter of the wire is 0.0508 cm (0.020"). *Id.* A wire diameter of 0.0508 cm results in an unmodified reactive surface area of 0.002 cm^2 ($SA_{unmodified} = \pi r^2$). Accordingly, the 0.002 cm^2 surface area of the Rhodes '874 publication falls within the range of 0.000084 cm^2 to about 0.016 cm^2.

Moreover, the Rhodes '874 publication also discloses modifying the wire electrode to resemble a "T" configuration at the end of the electrode, thereby changing the electrochemically

reactive surface area depending on the size of the "T". *Id.* at [0110]. Therefore, the resulting modified electrode can be 2-10, 2-25, 2-50, or 2-100 times the surface area of the unmodified wire electrode. *Id.* at [0110]. As such, the Rhodes '874 publication teaches electrodes with electroactive surfaces with areas ranging from about 0.004 cm^2 to about 0.02 cm^2, which fall within the claimed range, and thus anticipates the claimed limitation.

> a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and
>
> *Part of Claim 1*

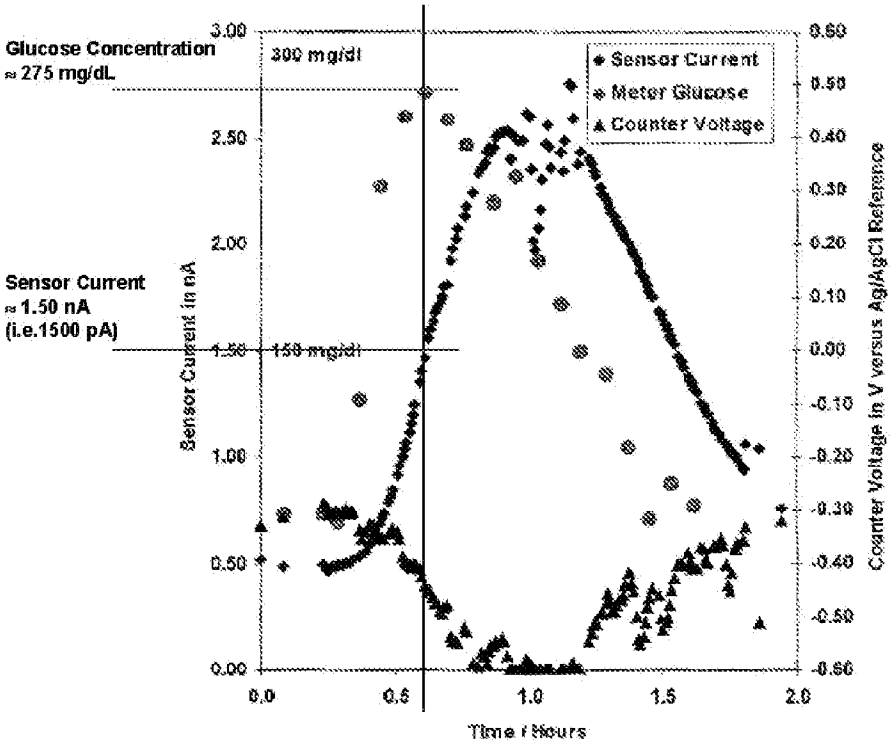
The Rhodes '874 publication teaches a multi-region membrane disposed over the electrode. See, for example, the Rhodes '874 publication, pg. 5, [0062] – pg. 8, [0108]; and FIGs. 2A-2F. The membrane includes a resistance domain configured to limit transport of glucose to the electrode. See, for example, pg. 6, [0082] – pg. 7, [0085].

> sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode, wherein the sensor electronics are configured to measure the current flow in at least a picoAmp range;
>
> wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL, and wherein the system is configured to measure the current flow associated with the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L.
>
> *Part of Claim 1*

The Rhodes '874 publication teaches sensor electronics operably connected to the electrode and configured to measure a current flow associate with the electrode. See, for example, the Rhodes '874 publication, FIG. 3; pg. 8, [0107] – pg. 9, [0115]. The sensor electronics are configured to measure the current flow in at least a picoAmp range. *Id.*

Further, the Rhodes '874 publication teaches that the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL. For example, the Rhodes '874 publication discloses an implantable glucose sensor that showed no oxygen dependence to oxygen concentrations as low as 0.1 mg/L, and a sensitivity of at least 5.5 pA/mg/dL, to increasing concentrations up to 400 mg/dL of glucose. See, for example, the Rhodes '874 publication, FIGs. 3 and 9; and pg. 11, [0131]-[0141].

FIG. 3 of the Rhodes '874 publication (reproduced below and annotated for clarity) shows a sensor system configured to have a sensor output of at least 5.5 pA/mg/dL, between 0-300 mg/dL. For example, at a glucose concentration of 275 mg/dL, the glucose sensor system of the Rhodes '874 publication has a sensor current of 1.5 nA (i.e., 1,500 pA). Therefore, the Rhodes '874 publication discloses a glucose sensor system that has a sensitivity of at least 5.5 pA/mg/dL. As such, the disclosed sensor sensitivity of at least 5.5 pA/mg/dL in the Rhodes '874 publication falls within the claimed range of about 1 pA/mg/dL to about 25 pA/mg/dL.



Finally, the Rhodes '874 publication teaches that the system is configured to measure the current flow associated with the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL, in a fluid with an oxygen concentration of less than about 0.6 mg/L. For example, the Rhodes '874 publication discloses that testing was conducted up to a glucose concentration of 400 mg/dL, with oxygen concentrations down to 0.1 mg/L. See, for example, the Rhodes '874 publication, EXAMPLE 2, pg. 10, [0131]-[0137]. In paragraph [0136], the Rhodes '874 publication states, "A glucose value was recorded for each device at decreasing oxygen concentrations from ambient to approximately 0.1 mg/L." In paragraph [0137], the Rhodes '874 publication states, "For example, at an oxygen concentration of about 0.5 mg/L, devices containing the silicone membrane are providing 100% output as compared to 80% output

for the control devices." As such, the Rhodes '874 publication discloses a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.6 mg/L, as called for in claim 1.

Because the Rhodes '874 publication teaches each and every feature of claim 1, the Rhodes '874 publication anticipates claim 1 under 35 U.S.C. § 102(b).

2. Dependent Claim 2

In addition to showing each and every feature of claim 1, the Rhodes '874 publication discloses the features of claim 2, which depends from claim 1, and thus anticipates claim 2 under 35 U.S.C. § 102(b).

> Claim 2. The glucose sensor system of claim 1, wherein the sensor electronics are configured to directly measure the current flow associated with the electrode.

The Rhodes '874 publication teaches sensor electronics configured to directly measure the current flow associated with the electrode. See, for example, the Rhodes '874 publication, pg. 9, [0113]-[0115].

3. Dependent Claim 4

In addition to showing each and every feature of claim 1, the Rhodes '874 publication discloses the features of claim 4, which depends from claim 1, and thus anticipates claim 4 under 35 U.S.C. § 102(b).

> Claim 4. The glucose sensor system of claim 1, wherein the membrane comprises a resistance domain configured with a permeability ratio of at least about 50:1 co-analyte to glucose concentration.

The Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having desired ratios of diffusion. See, for example, the Rhodes '874 publication, pgs. 6, [0082] – pg. 7, [0084]. Specifically, the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "a permeability ratio of at least about 50:1 co-analyte to glucose concentration."

4. Dependent Claim 5

In addition to showing each and every feature of claim 4, the Rhodes '874 publication discloses the features of claim 5, which depends from claim 4, and thus anticipates claim 5 under 35 U.S.C. § 102(b).

> Claim 5. The glucose sensor system of claim 4, wherein the permeability ratio is at least about 200:1.

The Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having desired ratios of diffusion. See, for example, the Rhodes '874 publication, pgs. 6, [0082] – pg. 7, [0084]. Specifically, the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "the permeability ratio is at least 200:1."

5. Dependent Claim 6

In addition to showing each and every feature of claim 1, the Rhodes '874 publication discloses the features of claim 6, which depends from claim 1, and thus anticipates claim 6 under 35 U.S.C. § 102(b).

> Claim 6. The glucose sensor system of claim 1, wherein the membrane comprises an enzyme.

The sensor of the Rhodes '874 publication includes an enzyme configured to catalyze a reaction of glucose and oxygen. See, for example, the Rhodes '874 publication, pg. 7, [0086]-[0088].

6. Dependent Claim 7

In addition to showing each and every feature of claim 1, the Rhodes '874 publication discloses the features of claim 7, which depends from claim 1, and thus anticipates claim 7 under 35 U.S.C. § 102(b).

> Claim 7. The glucose sensor system of claim 1, wherein the system is configured to determine a concentration of the glucose in a biological sample via measurement of hydrogen peroxide produced by an enzyme-catalyzed reaction of glucose with oxygen.

The Rhodes '874 publication teaches a sensor system configured to determine a concentration of the glucose in a biological sample via measurement of hydrogen peroxide

produced by an enzyme-catalyzed reaction of glucose with oxygen. See, for example, the Rhodes '874 publication, FIG. 1; pg. 3, [0022], [0027]; and pg. 6, [0073].

7. Dependent Claim 8

In addition to showing each and every feature of claim 1, the Rhodes '874 publication discloses the features of claim 8, which depends from claim 1, and thus anticipates claim 8 under 35 U.S.C. § 102(b).

> Claim 8. The glucose sensor system of claim 1, wherein the system is configured to have an operable life implanted within a host of at least about one week.

The Rhodes '874 publication teaches implantable glucose sensors employing multi-region membranes which have "enabled function of devices for over one year in vivo." The Rhodes '874 publication, pg. 5, [0061].

8. Dependent Claim 9

In addition to showing each and every feature of claim 1, the Rhodes '874 publication discloses the features of claim 9, which depends from claim 1, and thus anticipates claim 9 under 35 U.S.C. § 102(b).

> Claim 9. The glucose sensor system of claim 1, wherein the system is configured to measure glucose with substantial linearity at an oxygen concentration of less than about 0.3mg/L.

The Rhodes '874 publication discloses that testing was conducted up to a glucose concentration of 400 mg/dL, with oxygen concentrations down to 0.1 mg/L. See, for example, the Rhodes '874 publication, EXAMPLE 2, pg. 10, [0131]-[0137]. In paragraph [0136], the Rhodes '874 publication states, "A glucose value was recorded for each device at decreasing oxygen concentrations from ambient to approximately 0.1 mg/L." As such, the Rhodes '874 publication discloses a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.3 mg/L, as called for in claim 9.

9. Dependent Claim 11

In addition to showing each and every feature of claim 1, the Rhodes '874 publication discloses the features of claim 11, which depends from claim 1, and thus anticipates claim 11 under 35 U.S.C. § 102(b).

> Claim 11. The glucose sensor system of claim 1, wherein the membrane comprises a polyurethane.

The Rhodes '874 publication teaches the membrane comprising a polyurethane. See, for example, the Rhodes '874 publication, pg. 5, [0070].

10. Independent Claim 12

> Claim 12. A glucose sensor system comprising:
>
> *Part of Claim 12*

The Rhodes '874 publication teaches a glucose sensor system. See the Rhodes '874 publication, Abstract; FIG. 1; and pg. 2, [0012]-[0017].

> an electrode configured to measure a concentration of glucose in a host;
>
> *Part of Claim 12*

The Rhodes '874 publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See, for example, the Rhodes '874 publication, Abstract; and pg. 2, [0012]-[0017] and [0020].

> a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and
>
> *Part of Claim 12*

The Rhodes '874 publication teaches a multi-region membrane disposed over the electrode. See, for example, the Rhodes '874 publication, pg. 5, [0062] – pg. 8, [0108]; and FIGs. 2A-2F. The membrane includes a resistance domain configured to limit transport of glucose to the electrode. See, for example, pg. 6, [0082] – pg. 7, [0085].

> sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode;
>
> wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L, and wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL.
>
> *Part of Claim 12*

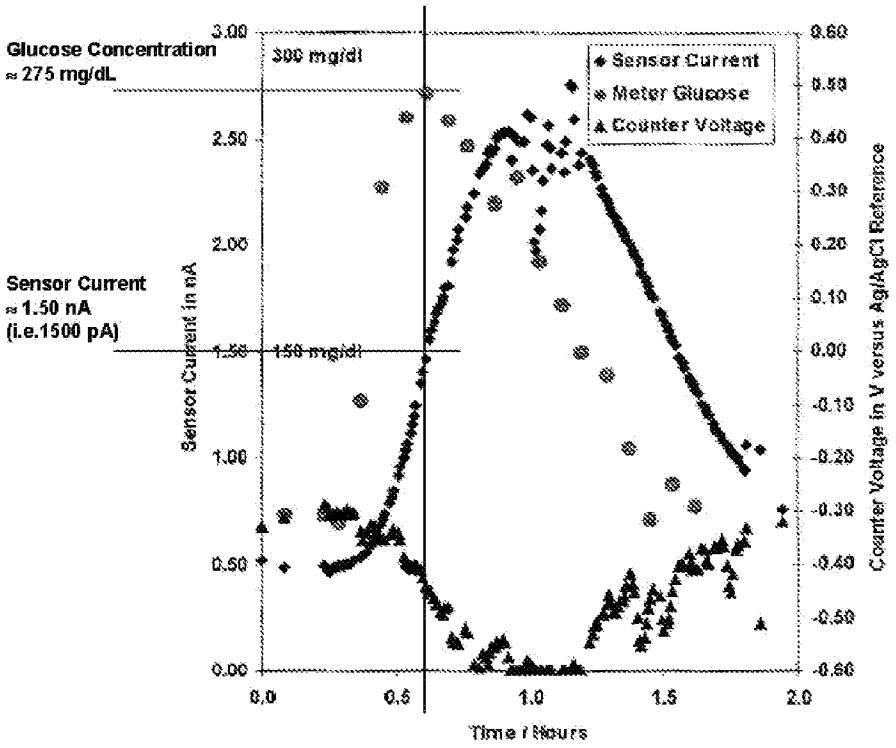
The Rhodes '874 publication teaches sensor electronics operably connected to the electrode and configured to measure a current flow associate with the electrode. See, for example, the Rhodes '874 publication, FIG. 3; pg. 8, [0107] – pg. 9, [0115].

Further, the Rhodes '874 publication teaches that the system is configured to measure the current flow associated with the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL, in a fluid with an oxygen concentration of less than about 0.6 mg/L. For example, the Rhodes '874 publication discloses that testing was conducted up to a glucose concentration of 400 mg/dL, with oxygen concentrations down to 0.1 mg/L. See, for example, the Rhodes '874 publication, EXAMPLE 2, pg. 10, [0131]-[0137]. In paragraph [0136], the Rhodes '874 publication states, "A glucose value was recorded for each device at decreasing oxygen concentrations from ambient to approximately 0.1 mg/L." In paragraph [0137], the Rhodes '874 publication states, "For example, at an oxygen concentration of about 0.5 mg/L, devices containing the silicone membrane are providing 100% output as compared to 80% output for the control devices." As such, the Rhodes '874 publication discloses a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.6 mg/L, as called for in claim 12.

Finally, the Rhodes '874 publication teaches that the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL. For example, the Rhodes '874 publication discloses an implantable glucose sensor that showed no oxygen dependence to oxygen concentrations as low as 0.1 mg/L, and a sensitivity of at least 5.5 pA/mg/dL, to increasing concentrations up to 400 mg/dL of glucose. See, for example, the Rhodes '874 publication, FIGs. 3 and 9; and pg. 11, [0131]-[0141].

FIG. 3 of the Rhodes '874 publication (reproduced below and annotated for clarity) shows a sensor system configured to have a sensor output of at least 5.5 pA/mg/dL, between 0-

300 mg/dL. For example, at a glucose concentration of 275 mg/dL, the glucose sensor system of the Rhodes '874 publication has a sensor current of 1.5 nA (i.e., 1,500 pA). Therefore, the Rhodes '874 publication discloses a glucose sensor system that has a sensitivity of at least 5.5 pA/mg/dL. As such, the disclosed sensor sensitivity of at least 5.5 pA/mg/dL in the Rhodes '874 publication falls within the claimed range of about 1 pA/mg/dL to about 25 pA/mg/dL.



11. Dependent Claim 13

In addition to showing each and every feature of claim 12, the Rhodes '874 publication discloses the features of claim 13, which depends from claim 12, and thus anticipates claim 13 under 35 U.S.C. § 102(b).

> Claim 13. The glucose sensor system of claim 12, wherein the electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2.

The Rhodes '874 publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See, for example, the Rhodes '874 publication , Abstract; and pg. 2, [0012]-[0017] and [0020]. The electrode comprises an exposed electroactive

surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2. See, for example, the Rhodes '874 publication, pg. 3, [0022]; and pgs. 8-9, [0110]-[0112]. More specifically, the Rhodes '874 publication describes the use of a wire electrode with a modified reactive surface. *See Id.* at [0112]. The diameter of the wire is 0.0508 cm (0.020"). *Id.* A wire diameter of 0.0508 cm results in an unmodified reactive surface area of 0.002 cm^2 ($SA_{unmodified} = \pi r^2$). Accordingly, the 0.002 cm^2 surface area of the Rhodes '874 publication falls within the range of 0.000084 cm^2 to about 0.016 cm^2.

Moreover, the Rhodes '874 publication also discloses modifying the wire electrode to resemble a "T" configuration at the end of the electrode, thereby changing the electrochemically reactive surface area depending on the size of the "T". *Id.* at [0110]. Therefore, the resulting modified electrode can be 2-10, 2-25, 2-50, or 2-100 times the surface area of the unmodified wire electrode. *Id.* at [0110]. As such, the Rhodes '874 publication teaches electrodes with electroactive surfaces with areas ranging from about 0.004 cm^2 to about 0.02 cm^2, which fall within the claimed range and thus anticipate the claimed limitation.

12. Dependent Claim 14

In addition to showing each and every feature of claim 12, the Rhodes '874 publication discloses the features of claim 14, which depends from claim 12, and thus anticipates claim 14 under 35 U.S.C. § 102(b).

> Claim 14. The glucose sensor system of claim 12, wherein the membrane comprises a resistance domain configured with a permeability ratio of at least about 50:1 co-analyte to glucose concentration.

The Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having desired ratios of diffusion. See, for example, the Rhodes '874 publication, pgs. 6, [0082] – pg. 7, [0084]. Specifically, the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "a permeability ratio of at least about 50:1 co-analyte to glucose concentration."

13. Dependent Claim 15

In addition to showing each and every feature of claim 14, the Rhodes '874 publication discloses the features of claim 15, which depends from claim 14, and thus anticipates claim 15 under 35 U.S.C. § 102(b).

> Claim 15. The glucose sensor system of claim 14, wherein the permeability ratio is at least about 200:1.

The Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having desired ratios of diffusion. See, for example, the Rhodes '874 publication, pgs. 6, [0082] – pg. 7, [0084]. Specifically, the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "the permeability ratio is at least about 200:1."

14. Dependent Claim 16

In addition to showing each and every feature of claim 12, the Rhodes '874 publication discloses the features of claim 16, which depends from claim 12, and thus anticipates claim 16 under 35 U.S.C. § 102(b).

> Claim 16. The glucose sensor system of claim 12, wherein the membrane comprises an enzyme.

The sensor of the Rhodes '874 publication includes an enzyme configured to catalyze a reaction of glucose and oxygen. See, for example, the Rhodes '874 publication, pg. 7, [0086]-[0088].

15. Dependent Claim 17

In addition to showing each and every feature of claim 12, the Rhodes '874 publication discloses the features of claim 17, which depends from claim 12, and thus anticipates claim 17 under 35 U.S.C. § 102(b).

> Claim 17. The glucose sensor system of claim 12, wherein the glucose sensitivity is from about 1 pA/mg/dL to about 10 pA/mg/dL.

The Rhodes '874 publication discloses a sensor system configured to have a sensor output of at least 5.5 pA/mg/dL between 0-300 mg/dL. As such, the disclosed sensor sensitivity

of at least 5.5 pA/mg/dL falls within the claimed range of about 1 pA/mg/dL to about 10 pA/mg/dL.

16. Dependent Claim 18

In addition to showing each and every feature of claim 12, the Rhodes '874 publication discloses the features of claim 18, which depends from claim 12, and thus anticipates claim 18 under 35 U.S.C. § 102(b).

> Claim 18. The glucose sensor system of claim 12, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.15 mg/L.

The Rhodes '874 publication discloses that testing was conducted up to a glucose concentration of 400 mg/dL, with oxygen concentrations down to 0.1 mg/L. See, for example, the Rhodes '874 publication, EXAMPLE 2, pg. 10, [0131]-[0137]. In paragraph [0136], the Rhodes '874 publication states, "A glucose value was recorded for each device at decreasing oxygen concentrations from ambient to approximately 0.1 mg/L." As such, the Rhodes '874 publication discloses a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.15 mg/L, as called for in claim 18.

17. Dependent Claim 21

In addition to showing each and every feature of claim 12, the Rhodes '874 publication discloses the features of claim 21, which depends from claim 12, and thus anticipates claim 21 under 35 U.S.C. § 102(b).

> Claim 21 The glucose sensor system of claim 12, wherein the sensor electronics are configured to directly measure the current flow associated with the electrode.

The Rhodes '874 publication teaches sensor electronics configured to directly measure the current flow associated with the electrode. See, for example, the Rhodes '874 publication, pg. 9, [0113]-[0115].

18. Dependent Claim 23

In addition to showing each and every feature of claim 12, the Rhodes '874 publication discloses the features of claim 23, which depends from claim 12, and thus anticipates claim 23 under 35 U.S.C. § 102(b).

> Claim 23. The glucose sensor system of claim 12, wherein the system is configured to determine a concentration of glucose in a biological sample via measurement of hydrogen peroxide produced by an enzyme-catalyzed reaction of glucose with oxygen.

The Rhodes '874 publication teaches a sensor system configured to determine a concentration of the glucose in a biological sample via measurement of hydrogen peroxide produced by an enzyme-catalyzed reaction of glucose with oxygen. See, for example, the Rhodes '874 publication, FIG. 1; pg. 3, [0022], [0027]; and pg. 6, [0073].

19. Dependent Claim 24

In addition to showing each and every feature of claim 12, the Rhodes '874 publication discloses the features of claim 24, which depends from claim 12, and thus anticipates claim 24 under 35 U.S.C. § 102(b).

> Claim 24. The glucose sensor system of claim 12, wherein the system is configured to have an operable life implanted within a host of at least about one week.

The Rhodes '874 publication teaches implantable glucose sensors employing multi-region membranes which have "enabled function of devices for over one year in vivo." The Rhodes '874 publication, pg. 5, [0061].

20. Dependent Claim 25

In addition to showing each and every feature of claim 12, the Rhodes '874 publication discloses the features of claim 25, which depends from claim 12, and thus anticipates claim 25 under 35 U.S.C. § 102(b).

> Claim 25. The glucose sensor system of claim 12, wherein the system is configured to measure glucose with substantial linearity at an oxygen concentration of less than about 0.3mg/L.

The Rhodes '874 publication discloses that testing was conducted up to a glucose concentration of 400 mg/dL, with oxygen concentrations down to 0.1 mg/L. See, for example,

the Rhodes '874 publication, EXAMPLE 2, pg. 10, [0131]-[0137]. In paragraph [0136], the Rhodes '874 publication states, "A glucose value was recorded for each device at decreasing oxygen concentrations from ambient to approximately 0.1 mg/L." As such, the Rhodes '874 publication discloses a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.3 mg/L, as called for in claim 25.

21. Dependent Claim 27

In addition to showing each and every feature of claim 12, the Rhodes '874 publication discloses the features of claim 27, which depends from claim 12, and thus anticipates claim 27 under 35 U.S.C. § 102(b).

> Claim 27. The glucose sensor system of claim 12, wherein the membrane comprises a polyurethane.

The Rhodes '874 publication teaches the membrane comprising a polyurethane. See, for example, the Rhodes '874 publication, pg. 5, [0070].

22. Independent Claim 28

> Claim 28. A glucose sensor system comprising:
>
> *Part of Claim 28*

The Rhodes '874 publication teaches a glucose sensor system. See the Rhodes '874 publication, Abstract; FIG. 1; and pg. 2, [0012]-[0017].

> an electrode configured to measure a concentration of glucose in a host;
>
> *Part of Claim 28*

The Rhodes '874 publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See, for example, the Rhodes '874 publication, Abstract; and pg. 2, [0012]-[0017] and [0020].

> a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and
>
> *Part of Claim 28*

The Rhodes '874 publication teaches a multi-region membrane disposed over the electrode. See, for example, the Rhodes '874 publication, pg. 5, [0062] – pg. 8, [0108]; and

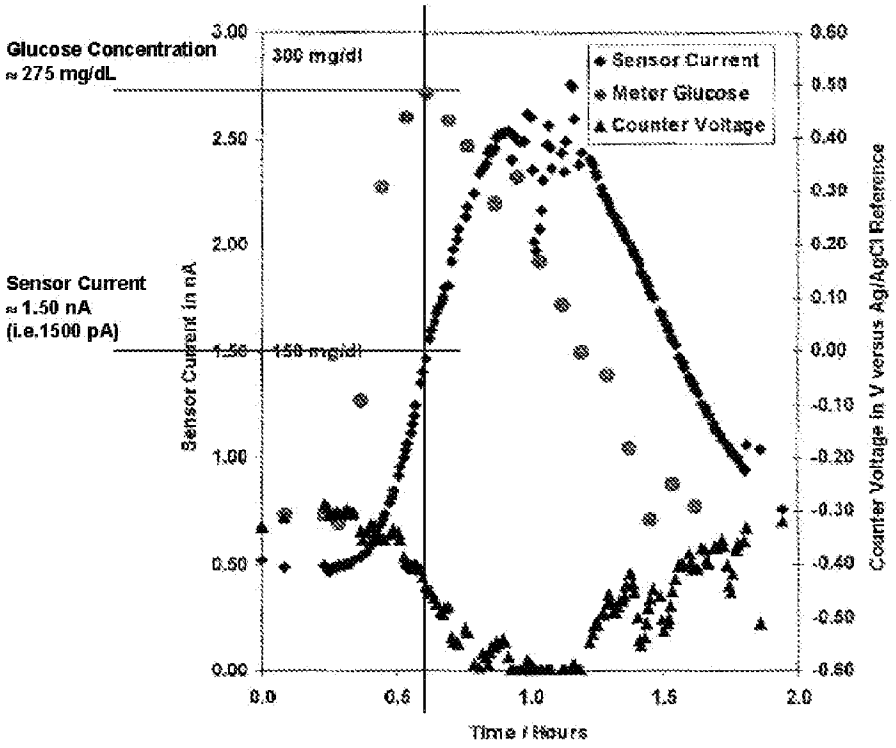
FIGs. 2A-2F. The membrane includes a resistance domain configured to limit transport of glucose to the electrode. See, for example, pg. 6, [0082] – pg. 7, [0085].

> sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode;
>
> wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL, and wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L.
>
> *Part of Claim 28*

The Rhodes '874 publication teaches sensor electronics operably connected to the electrode and configured to measure a current flow associate with the electrode. See, for example, the Rhodes '874 publication, FIG. 3; pg. 8, [0107] – pg. 9, [0115].

Further, the Rhodes '874 publication teaches that the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL. For example, the Rhodes '874 publication discloses an implantable glucose sensor that showed no oxygen dependence to oxygen concentrations as low as 0.1 mg/L, and a sensitivity of at least 5.5 pA/mg/dL, to increasing concentrations up to 400 mg/dL of glucose. See, for example, the Rhodes '874 publication, FIGs. 3 and 9; and pg. 11, [0131]-[0141].

FIG. 3 of the Rhodes '874 publication (reproduced below and annotated for clarity) shows a sensor system configured to have a sensor output of at least 5.5 pA/mg/dL, between 0-300 mg/dL. For example, at a glucose concentration of 275 mg/dL, the glucose sensor system of the Rhodes '874 publication has a sensor current of 1.5 nA (i.e., 1,500 pA). Therefore, the Rhodes '874 publication discloses a glucose sensor system that has a sensitivity of at least 5.5 pA/mg/dL. As such, the disclosed sensor sensitivity of at least 5.5 pA/mg/dL in the Rhodes '874 publication falls within the claimed range of about 1 pA/mg/dL to about 100 pA/mg/dL.



Finally, the Rhodes '874 publication discloses that testing was conducted up to a glucose concentration of 400 mg/dL, with oxygen concentrations down to 0.1 mg/L. See, for example, the Rhodes '874 publication, EXAMPLE 2, pg. 10, [0131]-[0137]. In paragraph [0136], the Rhodes '874 publication states, "A glucose value was recorded for each device at decreasing oxygen concentrations from ambient to approximately 0.1 mg/L." As such, the Rhodes '874 publication discloses a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.3 mg/L, as called for in claim 28.

23. Dependent Claim 29

In addition to showing each and every feature of claim 28, the Rhodes '874 publication discloses the features of claim 29, which depends from claim 28, and thus anticipates claim 29 under 35 U.S.C. § 102(b).

> Claim 29. The glucose sensor system of claim 28, wherein the electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2.

The Rhodes '874 publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See, for example, the Rhodes '874 publication , Abstract; and pg. 2, [0012]-[0017] and [0020]. The electrode comprises an exposed electroactive

surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2. See, for example, the Rhodes '874 publication, pg. 3, [0022]; and pgs. 8-9, [0110]-[0112]. More specifically, the Rhodes '874 publication describes the use of a wire electrode with a modified reactive surface. *See Id.* at [0112]. The diameter of the wire is 0.0508 cm (0.020"). *Id.* A wire diameter of 0.0508 cm results in an unmodified reactive surface area of 0.002 cm^2 ($SA_{unmodified} = \pi r^2$). Accordingly, the 0.002 cm^2 surface area of the Rhodes '874 publication falls within the range of 0.000084 cm^2 to about 0.016 cm^2.

Moreover, the Rhodes '874 publication also discloses modifying the wire electrode to resemble a "T" configuration at the end of the electrode, thereby changing the electrochemically reactive surface area depending on the size of the "T". *Id.* at [0110]. Therefore, the resulting modified electrode can be 2-10, 2-25, 2-50, or 2-100 times the surface area of the unmodified wire electrode. *Id.* at [0110]. As such, the Rhodes '874 publication teaches electrodes with electroactive surfaces with areas ranging from about 0.004 cm^2 to about 0.02 cm^2, which fall within the claimed range, and thus anticipates the claimed limitation.

24. Dependent Claim 30

In addition to showing each and every feature of claim 28, the Rhodes '874 publication discloses the features of claim 30, which depends from claim 28, and thus anticipates claim 30 under 35 U.S.C. § 102(b).

> Claim 30. The glucose sensor system of claim 28, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.15 mg/L.

The Rhodes '874 publication discloses that testing was conducted up to a glucose concentration of 400 mg/dL, with oxygen concentrations down to 0.1 mg/L. See, for example, the Rhodes '874 publication, EXAMPLE 2, pg. 10, [0131]-[0137]. In paragraph [0136], the Rhodes '874 publication states, "A glucose value was recorded for each device at decreasing oxygen concentrations from ambient to approximately 0.1 mg/L." As such, the Rhodes '874 publication discloses a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.15 mg/L, as called for in claim 30.

25. Dependent Claim 33

In addition to showing each and every feature of claim 28, the Rhodes '874 publication discloses the features of claim 33, which depends from claim 28, and thus anticipates claim 33 under 35 U.S.C. § 102(b).

> Claim 33. The glucose sensor system of claim 28, wherein the sensor electronics are configured to directly measure the current flow associated with the electrode.

The Rhodes '874 publication teaches sensor electronics configured to directly measure the current flow associated with the electrode. See, for example, the Rhodes '874 publication, pg. 9, [0113]-[0115].

26. Dependent Claim 35

In addition to showing each and every feature of claim 28, the Rhodes '874 publication discloses the features of claim 35, which depends from claim 28, and thus anticipates claim 35 under 35 U.S.C. § 102(b).

> Claim 35. The glucose sensor system of claim 28, wherein the membrane comprises a resistance domain configured with a permeability ratio of at least about 50:1 co-analyte to glucose concentration.

The Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having desired ratios of diffusion. See, for example, the Rhodes '874 publication, pgs. 6, [0082] – pg. 7, [0084]. Specifically, the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "a permeability ratio of at least about 50:1 co-analyte to glucose concentration."

27. Dependent Claim 36

In addition to showing each and every feature of claim 35, the Rhodes '874 publication discloses the features of claim 36, which depends from claim 35, and thus anticipates claim 36 under 35 U.S.C. § 102(b).

> Claim 36. The glucose sensor system of claim 35, wherein the permeability ratio is at least about 200:1.

The Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having desired ratios of diffusion. See, for example, the Rhodes '874 publication, pgs. 6, [0082] – pg. 7, [0084]. Specifically, the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "the permeability ratio is at least about 200:1."

28. Dependent Claim 37

In addition to showing each and every feature of claim 28, the Rhodes '874 publication discloses the features of claim 37, which depends from claim 28, and thus anticipates claim 37 under 35 U.S.C. § 102(b).

> Claim 37. The glucose sensor system of claim 28, wherein the membrane comprises an enzyme.

The sensor of the Rhodes '874 publication includes an enzyme configured to catalyze a reaction of glucose and oxygen. See, for example, the Rhodes '874 publication, pg. 7, [0086]-[0088].

29. Dependent Claim 38

In addition to showing each and every feature of claim 28, the Rhodes '874 publication discloses the features of claim 38, which depends from claim 28, and thus anticipates claim 38 under 35 U.S.C. § 102(b).

> Claim 38. The glucose sensor system of claim 28, wherein the system is configured to determine a concentration of glucose in a biological sample via measurement of hydrogen peroxide produced by an enzyme-catalyzed reaction of glucose with oxygen.

The Rhodes '874 publication teaches a sensor system configured to determine a concentration of the glucose in a biological sample via measurement of hydrogen peroxide produced by an enzyme-catalyzed reaction of glucose with oxygen. See, for example, the Rhodes '874 publication, FIG. 1; pg. 3, [0022], [0027]; and pg. 6, [0073].

30. Dependent Claim 39

In addition to showing each and every feature of claim 28, the Rhodes '874 publication discloses the features of claim 39, which depends from claim 28, and thus anticipates claim 39 under 35 U.S.C. § 102(b).

> Claim 39. The glucose sensor system of claim 28, wherein the system is configured to have an operable life implanted within a host of at least about one week.

The Rhodes '874 publication teaches implantable glucose sensors employing multi-region membranes which have "enabled function of devices for over one year in vivo." The Rhodes '874 publication, pg. 5, [0061].

31. Dependent Claim 41

In addition to showing each and every feature of claim 28, the Rhodes '874 publication discloses the features of claim 41, which depends from claim 28, and thus anticipates claim 41 under 35 U.S.C. § 102(b).

> Claim 41. The glucose sensor system of claim 28, wherein the membrane comprises a polyurethane.

The Rhodes '874 publication teaches the membrane comprising a polyurethane. See, for example, the Rhodes '874 publication, pg. 5, [0070].

B. Claims 3, 22, and 34 are obvious under 35 U.S.C. § 103 in view of the Rhodes '874 publication and the Jung '472 publication.

Claims 3, 22, and 34 are unpatentable under 35 U.S.C. § 103(a) over the Rhodes '874 publication in view of the Jung '472 publication. Sections VI.B.1 – VI.B.3 detail how claims 3, 22, and 34 are rendered obvious by the teachings of the Rhodes '874 publication and the Jung '472 publication. For the examiner's convenience, the arguments presented below are summarized in the table provided in **Exhibit J**.

1. Dependent Claim 3

As outlined above, the Rhodes '874 publication teaches each and every feature of claim 1. The combination of the Rhodes '874 publication and the Jung '472 publication discloses the

features of claim 3, which depends from claim 1. As such, claim 3 is unpatentable under 35 U.S.C. § 103(a).

> Claim 3. The glucose sensor system of claim 1, further comprising an analog-to-digital converter configured to translate the current flow measurement to a digital signal.

While the Rhodes '874 publication does not explicitly state that the sensor electronics use an analog-to-digital converter, the Jung '472 publication shows how an analog-to-digital converter can be used in a glucose sensor to translate the current flow measurement to a digital signal. See, for example, the Jung '472 publication, [0034]-[0035]. One of skill in the art would understand that in order to convert the current flow from an analog signal to a digital signal, an analog-to-digital converter is necessary. In accordance with the teachings of the Jung '472 publication, one of skill in the art would recognize how to use an analog-to-digital converter in the sensor electronics of the Rhodes '874 publication. The sensor of claim 3 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 3 would have been obvious to one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication and the Jung '472 publication. Claim 3 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

2. Dependent Claim 22

As outlined above, the Rhodes '874 publication teaches each and every feature of claim 12. The combination of the Rhodes '874 publication and the Jung '472 publication discloses the features of claim 22, which depends from claim 12. As such, claim 22 is unpatentable under 35 U.S.C. § 103(a).

> Claim 22. The glucose sensor system of claim 12, further comprising an analog-to-digital converter configured to translate the current flow measurement to a digital signal.

While the Rhodes '874 publication does not explicitly state that the sensor electronics use an analog-to-digital converter, the Jung '472 publication shows how an analog-to-digital converter can be used in a glucose sensor to translate the current flow measurement to a digital signal. See, for example, the Jung '472 publication, [0034]-[0035]. One of skill in the art would understand that in order to convert the current flow from an analog signal to a digital signal, an analog-to-digital converter is necessary. In accordance with the teachings of the Jung '472

publication, one of skill in the art would recognize how to use an analog-to-digital converter in the sensor electronics of the Rhodes '874 publication. The sensor of claim 22 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 22 would have been obvious to one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication and the Jung '472 publication. Claim 22 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

3. Dependent Claim 34

As outlined above, the Rhodes '874 publication teaches each and every feature of claim 28. The combination of the Rhodes '874 publication and the Jung '472 publication discloses the features of claim 34, which depends from claim 28. As such, claim 34 is unpatentable under 35 U.S.C. § 103(a).

> Claim 34. The glucose sensor system of claim 28, further comprising an analog-to-digital converter configured to translate the current flow measurement to a digital signal.

While the Rhodes '874 publication does not explicitly state that the sensor electronics use an analog-to-digital converter, the Jung '472 publication shows how an analog-to-digital converter can be used in a glucose sensor to translate the current flow measurement to a digital signal. See, for example, the Jung '472 publication, [0034]-[0035]. One of skill in the art would understand that in order to convert the current flow from an analog signal to a digital signal, an analog-to-digital converter is necessary. In accordance with the teachings of the Jung '472 publication, one of skill in the art would recognize how to use an analog-to-digital converter in the sensor electronics of the Rhodes '874 publication. The sensor of claim 34 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 34 would have been obvious to one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication and the Jung '472 publication. Claim 34 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

C. Claims 10, 26, and 40 are obvious under 35 U.S.C. § 103 in view of the Rhodes '874 publication and the Sternberg publication.

Claims 10, 26, and 40 are unpatentable under 35 U.S.C. § 103(a) over the Rhodes '874 publication in view of the Sternberg publication. Sections VI.C.1 – VI.C.3 detail how claims 10, 26, and 40 are rendered obvious by the teachings of the Rhodes '874 publication and the Sternberg publication. For the examiner's convenience, the arguments presented below are summarized in the table provided in **Exhibit K**.

1. Dependent Claim 10

As outlined above, the Rhodes '874 publication teaches each and every feature of claim 1. The combination of the Rhodes '874 publication and the Sternberg publication discloses the features of claim 10, which depends from claim 1. As such, claim 10 is unpatentable under 35 U.S.C. § 103(a).

> Claim 10. The glucose sensor system of claim 1, wherein the system is configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation

The Rhodes '874 publication describes the sensor as being used *in vivo* for over one year. The Rhodes '874 publication teaches the use of an immobilized glucose oxidase (GOx) as the enzyme. See, for example, the Rhodes '874 publication, [0004] and [0127]. The Sternberg publication describes three procedures for preparing electrodes with GOx (i.e., the enzyme employed in the sensor of the Rhodes '874 publication). See, for example, the Sternberg publication, pgs. 2782-83, and Table I. Procedures "a," "b," and "c" contain 3.0 ± 1.2 μg, 6.4 ± 2.2 μg, and 10 ± 1.4 μg of GOx, respectively. *Id.* More specifically, procedure "a" provides 3.8 ± 1.5 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 3.0 ± 1.2 μg of enzyme; procedure "b" provides 8.0 ± 2.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 6.4 ± 2.2 μg of enzyme; and procedure "c" provides 13 ± 1.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 10 ± 1.4 μg of enzyme.

As discussed on page 2784 of the Sternberg publication, "Figure 5 compares the time-dependent loss of enzymatic activity with the loss of enzyme mass from the membrane surface." The line noted with the "X" markers in Figure 5 (reproduced below) illustrates the consumption of GOx over about 15 days of continuous use.

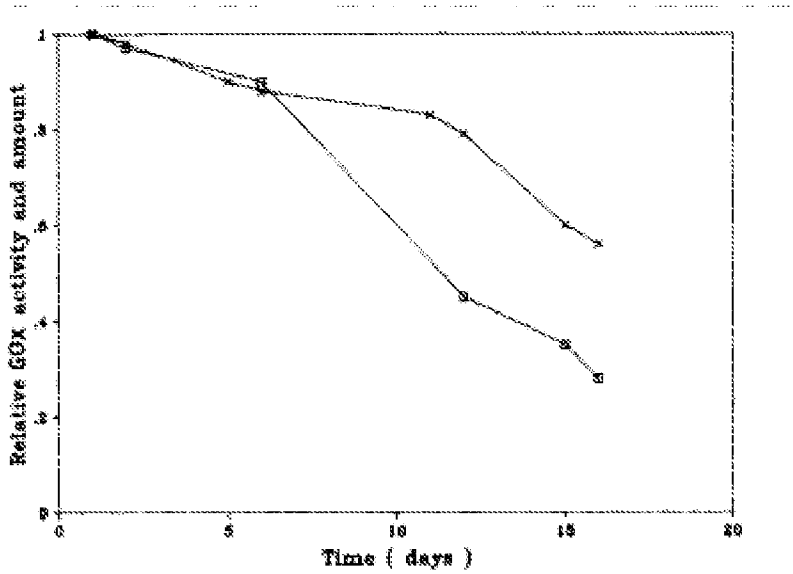


Figure 5. Relative evolution of surface GOx activity (O) and ^{125}I–GOx (X) in a CA–BSA–PBQ–GOx membrane not treated with lysine after coupling.

As shown in Figure 5, the relative consumption of GOx over the first seven days of use is between about 10% and about 15%. Enzyme prepared in accordance with procedure "a" would begin with 3.0 ± 1.2 μg, and result in a consumption of about 0.18-0.63 μg. Enzyme prepared in accordance with procedure "b" would begin with 6.4 ± 2.2 μg, and result in consumption of about 0.42-1.3 μg. Enzyme prepared in accordance with procedure "c" would begin with 10 ± 1.4 μg, and result in consumption of about 0.86-1.7 μg. As such, the Sternberg publication teaches how to configure a system to consume a range of enzyme mass from about 0.18-1.7 μg over 7 days of continuous operation.

One of skill in the art, in view of the teachings of the Sternberg publication, would thus appreciate how to configure a sensor "such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation." In other words, the Sternberg publication teaches three preparation procedures that can be used to prepare the GOx used in the Rhodes '874 publication in order to meet the claimed consumption limitation. The sensor of claim 10 offers no more than the predictable use of prior art elements according to their established functions.

As such, claim 10 would have been obvious to one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication and the Sternberg publication. Claim 10 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

2. Dependent Claim 26

As outlined above, the Rhodes '874 publication teaches each and every feature of claim 12. The combination of the Rhodes '874 publication and the Sternberg publication discloses the features of claim 26, which depends from claim 12. As such, claim 26 is unpatentable under 35 U.S.C. § 103(a).

> Claim 26. The glucose sensor system of claim 12, wherein the system is configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation.

The Rhodes '874 publication describes the sensor as being used *in vivo* for over one year. The Rhodes '874 publication teaches the use of an immobilized glucose oxidase (GOx) as the enzyme. See, for example, the Rhodes '874 publication, [0004] and [0127]. The Sternberg publication describes three procedures for preparing electrodes with GOx (i.e., the enzyme employed in the sensor of the Rhodes '874 publication). See, for example, the Sternberg publication, pgs. 2782-83, and Table I. Procedures "a," "b," and "c" contain 3.0 ± 1.2 μg, 6.4 ± 2.2 μg, and 10 ± 1.4 μg of GOx, respectively. *Id.* More specifically, procedure "a" provides 3.8 ± 1.5 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 3.0 ± 1.2 μg of enzyme; procedure "b" provides 8.0 ± 2.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 6.4 ± 2.2 μg of enzyme; and procedure "c" provides 13 ± 1.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 10 ± 1.4 μg of enzyme.

As discussed on page 2784 of the Sternberg publication, "Figure 5 compares the time-dependent loss of enzymatic activity with the loss of enzyme mass from the membrane surface." The line noted with the "X" markers in Figure 5 (reproduced below) illustrates the consumption of GOx over about 15 days of continuous use.

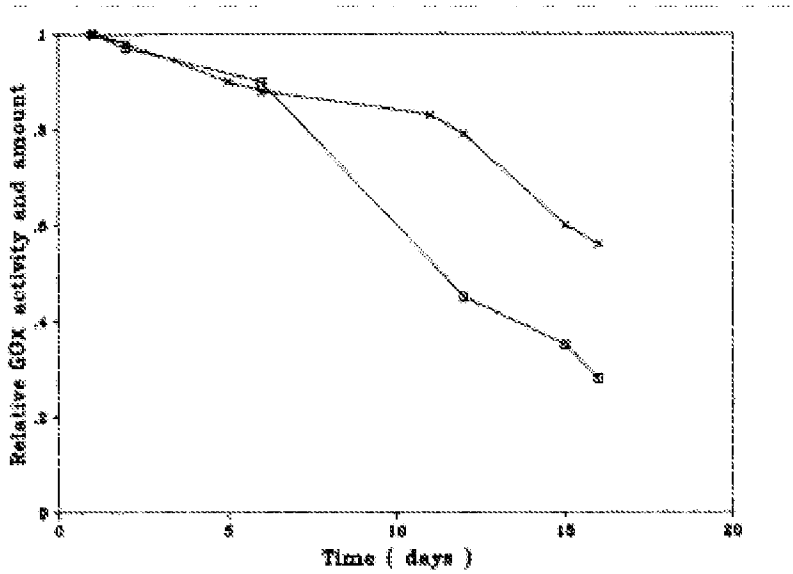


Figure 5. Relative evolution of surface GOx activity (O) and ^{125}I–GOx (X) in a CA–BSA–PBQ–GOx membrane not treated with lysine after coupling.

As shown in Figure 5, the relative consumption of GOx over the first seven days of use is between about 10% and about 15%. Enzyme prepared in accordance with procedure "a" would begin with 3.0 ± 1.2 μg, and result in a consumption of about 0.18-0.63 μg. Enzyme prepared in accordance with procedure "b" would begin with 6.4 ± 2.2 μg, and result in consumption of about 0.42-1.3 μg. Enzyme prepared in accordance with procedure "c" would begin with 10 ± 1.4 μg, and result in consumption of about 0.86-1.7 μg. As such, the Sternberg publication teaches how to configure the system to consume a range of enzyme mass from about 0.18-1.7 μg over 7 days of continuous operation.

One of skill in the art, in view of the teachings of the Sternberg publication, would thus appreciate how to configure a sensor "such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation." In other words, the Sternberg publication teaches three preparation procedures that can be used to prepare the GOx used in the Rhodes '874 publication in order to meet the claimed consumption limitation. The sensor of claim 26 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 26 would have been obvious to one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication and the Sternberg publication. Claim 26 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

3. Dependent Claim 40

As outlined above, the Rhodes '874 publication teaches each and every feature of claim 28. The combination of the Rhodes '874 publication and the Sternberg publication discloses the features of claim 40, which depends from claim 28. As such, claim 40 is unpatentable under 35 U.S.C. § 103(a).

> Claim 40. The glucose sensor system of claim 28, wherein the system is configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation.

The Rhodes '874 publication describes the sensor as being used *in vivo* for over one year. The Rhodes '874 publication teaches the use of an immobilized glucose oxidase (GOx) as the enzyme. See, for example, the Rhodes '874 publication, [0004] and [0127]. The Sternberg publication describes three procedures for preparing electrodes with GOx (i.e., the enzyme employed in the sensor of the Rhodes '874 publication). See, for example, the Sternberg publication, pgs. 2782-83, and Table I. Procedures "a," "b," and "c" contain 3.0 ± 1.2 μg, 6.4 ± 2.2 μg, and 10 ± 1.4 μg of GOx, respectively. *Id.* More specifically, procedure "a" provides 3.8 ± 1.5 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 3.0 ± 1.2 μg of enzyme; procedure "b" provides 8.0 ± 2.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 6.4 ± 2.2 μg of enzyme; and procedure "c" provides 13 ± 1.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 10 ± 1.4 μg of enzyme.

As discussed on page 2784 of the Sternberg publication, "Figure 5 compares the time-dependent loss of enzymatic activity with the loss of enzyme mass from the membrane surface." The line noted with the "X" markers in Figure 5 (reproduced below) illustrates the consumption of GOx over about 15 days of continuous use.

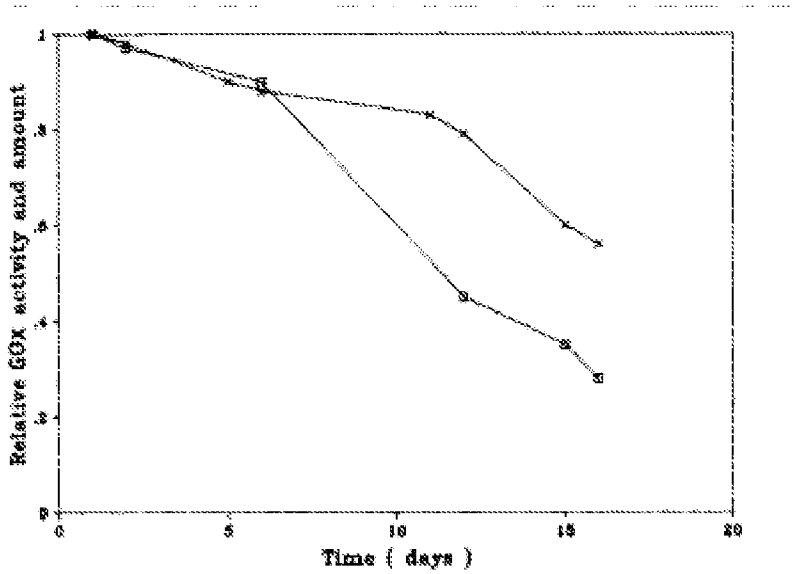


Figure 5. Relative evolution of surface GOx activity (O) and ^{125}I–GOx (X) in a CA–BSA–PBQ–GOx membrane not treated with lysine after coupling.

As shown in Figure 5, the relative consumption of GOx over the first seven days of use is between about 10% and about 15%. Enzyme prepared in accordance with procedure "a" would begin with 3.0 ± 1.2 μg, and result in a consumption of about 0.18-0.63 μg. Enzyme prepared in accordance with procedure "b" would begin with 6.4 ± 2.2 μg, and result in consumption of about 0.42-1.3 μg. Enzyme prepared in accordance with procedure "c" would begin with 10 ± 1.4 μg, and result in consumption of about 0.86-1.7 μg. As such, the Sternberg publication teaches how to configure the system to consume a range of enzyme mass from about 0.18-1.7 μg over 7 days of continuous operation.

One of skill in the art, in view of the teachings of the Sternberg publication, would thus appreciate how to configure a sensor "such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation." In other words, the Sternberg publication teaches three preparation procedures that can be used to prepare the GOx used in the Rhodes '874 publication in order to meet the claimed consumption limitation. The sensor of claim 40 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 40 would have been obvious to one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication and the Sternberg publication. Claim 40 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

D. Claims 1, 2, 4-9, 11-21, 23-25, 27-33, 35-39, and 41 are obvious under 35 U.S.C. § 103 in view of the Rhodes '874 publication and the Kusano publication.

Claims 1, 2, 4-9, 11-21, 23-25, 27-33, 35-39, and 41 are unpatentable under 35 U.S.C. § 103(a) over the Rhodes '874 publication in view of the Kusano publication. Sections VI.D.1 – VI.D.35 detail how claims 1, 2, 4-9, 11-21, 23-25, 27-33, 35-39, and 41 are rendered obvious by the teachings of the Rhodes '874 publication and the Kusano publication. For the examiner's convenience, the arguments presented below are summarized in the table provided in **Exhibit L**.

1. Independent Claim 1

Claim 1. A glucose sensor system comprising: *Part of Claim 1*

The Rhodes '874 publication teaches a glucose sensor system. See the Rhodes '874 publication, Abstract; FIG. 1; and pg. 2, [0012]-[0017].

The Kusano publication teaches a glucose sensor system. See, for example, the Kusano publication, Abstract, and FIGs. 3, 4, and 9.

an electrode configured to measure a concentration of glucose in a host, wherein the electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2; *Part of Claim 1*

The Rhodes '874 publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See, for example, the Rhodes '874 publication, Abstract; and pg. 2, [0012]-[0017] and [0020]. The electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2. See, for example, the Rhodes '874 publication, pg. 3, [0022]; and pgs. 8-9, [0110]-[0112]. More specifically, the Rhodes '874 publication describes the use of a wire electrode with a modified reactive surface. *See Id.* at [0112]. The diameter of the wire is 0.0508 cm (0.020"). *Id.* A wire diameter of 0.0508 cm results in an unmodified reactive surface area of 0.002 cm^2 ($SA_{unmodified} = \pi r^2$). Accordingly, the 0.002 cm^2 surface area of the Rhodes '874 publication falls within the range of 0.000084 cm^2 to about 0.016 cm^2.

Moreover, the Rhodes '874 publication also discloses modifying the wire electrode to resemble a "T" configuration at the end of the electrode, thereby changing the electrochemically reactive surface area depending on the size of the "T". *Id.* at [0110]. Therefore, the resulting

modified electrode can be 2-10, 2-25, 2-50, or 2-100 times the surface area of the unmodified wire electrode. *Id.* at [0110]. As such, the Rhodes '874 publication teaches electrodes with electroactive surfaces with areas ranging from about 0.004 cm^2 to about 0.02 cm^2, which fall within the claimed range, and thus anticipates the claimed limitation.

The Kusano publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See, for example, the Kusano publication, pgs. 2-3, and FIG. 2 (reproduced below).

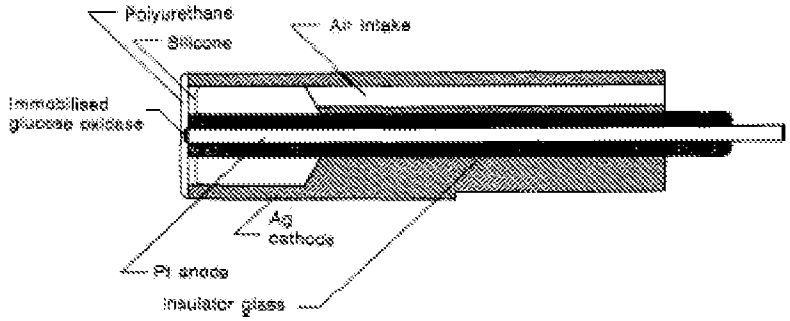


Figure 2. Schematic diagram of the experimental glucose electrode.

The Abstract of the Kusano publication, for example, states "[t]he electrode has been designed to be used with a percutaneous interface for future *in vivo* use."

The Kusano publication teaches an electroactive surface area that falls within the range of 0.000084 cm^2 to about 0.016 cm^2. Specifically, the Kusano publication teaches a working electrode with "0.5 μg of albumin-linked glucose oxidase [] immobilised at the tip" of a "Pt wire 0.5 mm in diameter." See the Kusano publication, Abstract. The surface area of the electroactive surface is therefore the surface area of the tip of the Pt wire, which is equal to 0.00196 cm^2 (Area = πr^2 = (3.14)(0.25mm)^2 = 0.196 mm^2 = 0.00196 cm^2). A surface area of 0.00196 cm^2 falls within the claimed range of about 0.000084 cm^2 to about 0.016 cm^2.

> a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and
>
> *Part of Claim 1*

The Rhodes '874 publication teaches a multi-region membrane disposed over the electrode. See, for example, the Rhodes '874 publication, pg. 5, [0062] – pg. 8, [0108]; and FIGs. 2A-2F. The membrane includes a resistance domain configured to limit transport of glucose to the electrode. See, for example, pg. 6, [0082] – pg. 7, [0085].

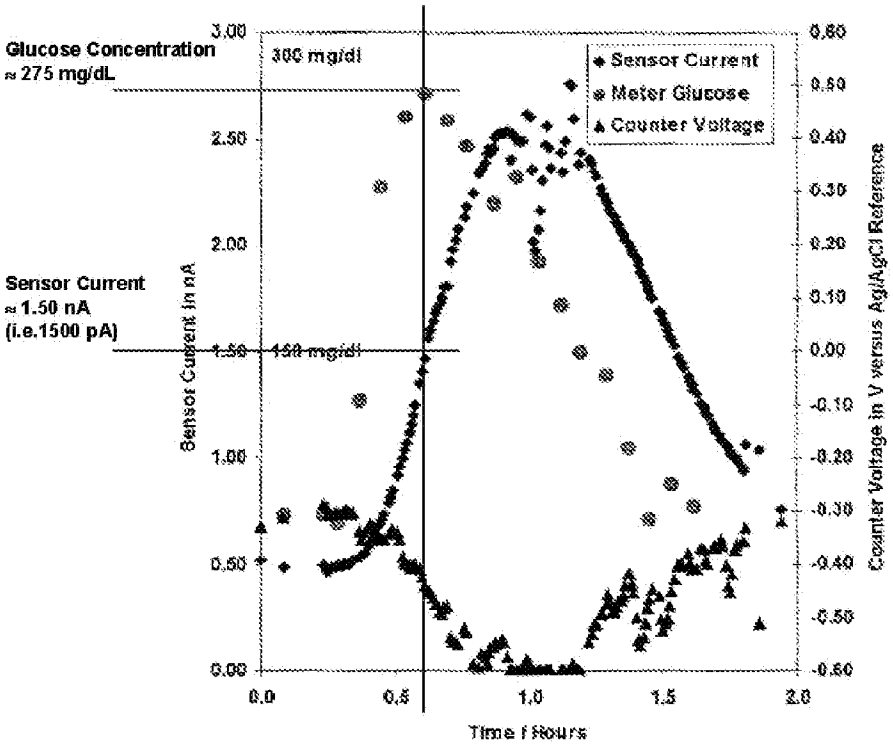
The Kusano publication teaches a polyurethane membrane disposed over the electrode. See, for example, FIG. 2 of the Kusano publication (above). The membrane includes a resistance domain configured to limit transport of glucose to the electrode. See, for example, the Kusano publication, pgs. 1-3.

> sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode, wherein the sensor electronics are configured to measure the current flow in at least a picoAmp range;
>
> wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL, and wherein the system is configured to measure the current flow associated with the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L.
>
> *Part of Claim 1*

The Rhodes '874 publication teaches sensor electronics operably connected to the electrode and configured to measure a current flow associate with the electrode. See, for example, the Rhodes '874 publication, FIG. 3; pg. 8, [0107] – pg. 9, [0115]. The sensor electronics are configured to measure the current flow in at least a picoAmp range. *Id.*

Further, the Rhodes '874 publication teaches that the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL. For example, the Rhodes '874 publication discloses an implantable glucose sensor that showed no oxygen dependence to oxygen concentrations as low as 0.1 mg/L, and a sensitivity of at least 5.5 pA/mg/dL, to increasing concentrations up to 400 mg/dL of glucose. See, for example, the Rhodes '874 publication, FIGs. 3 and 9; and pg. 11, [0131]-[0141].

FIG. 3 of the Rhodes '874 publication (reproduced below and annotated for clarity) shows a sensor system configured to have a sensor output of at least 5.5 pA/mg/dL, between 0-300 mg/dL. For example, at a glucose concentration of 275 mg/dL, the glucose sensor system of the Rhodes '874 publication has a sensor current of 1.5 nA (i.e., 1,500 pA). Therefore, the Rhodes '874 publication discloses a glucose sensor system that has a sensitivity of at least 5.5 pA/mg/dL. As such, the disclosed sensor sensitivity of at least 5.5 pA/mg/dL in the Rhodes '874 publication falls within the claimed range of about 1 pA/mg/dL to about 25 pA/mg/dL.



Finally, the Rhodes '874 publication teaches that the system is configured to measure the current flow associated with the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL, in a fluid with an oxygen concentration of less than about 0.6 mg/L. For example, the Rhodes '874 publication discloses that testing was conducted up to a glucose concentration of 400 mg/dL, with oxygen concentrations down to 0.1 mg/L. See, for example, the Rhodes '874 publication, EXAMPLE 2, pg. 10, [0131]-[0137]. In paragraph [0136], the Rhodes '874 publication states, "A glucose value was recorded for each device at decreasing oxygen concentrations from ambient to approximately 0.1 mg/L." In paragraph [0137], the Rhodes '874 publication states, "For example, at an oxygen concentration of about 0.5 mg/L, devices containing the silicone membrane are providing 100% output as compared to 80% output for the control devices." As such, the Rhodes '874 publication discloses a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.6 mg/L, as called for in claim 1.

The Kusano publication teaches sensor electronics operably connected to the electrode. The sensor electronics measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL, in a fluid with an oxygen concentration of less than about 0.6 mg/L. Specifically, the Kusano publication states, "The glucose electrode with

percutaneous interface described in this paper differs from [previously described electrodes] using a novel approach to overcome the lack of oxygen in the interstitial fluid." *Id.* The Kusano publication further states:

> The electrode has a linear response to glucose concentration at an electrode output current ranging from 0 to 20nA ***even when the oxygen concentration of the glucose solution is zero***. The use of polyurethane as a diffusion barrier to glucose limits the electrode output current at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) to 20 nA. Therefore, the electrode can measure glucose concentrations up to 500 mg dl^{-1} (27.8 mmol l^{-1}) ***with no oxygen*** dissolved in the glucose solution.

The Kusano publication, Abstract (emphasis added).

Figure 8 of the Kusano publication (reproduced below) shows a linear current measurement up to 500 mg/dL, even at 0 kPa of Po_2.

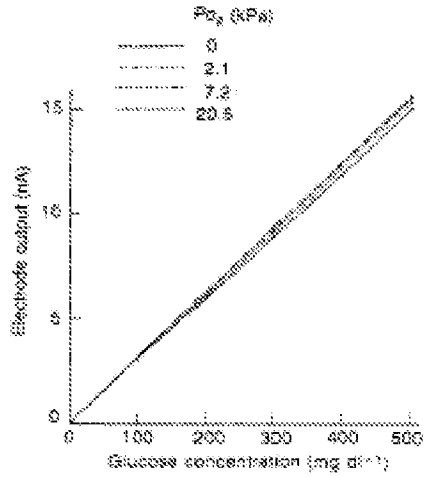


Figure 8. Electrode calibration curves under various Po_2.

The concluding remarks of the Kusano publication further state:

> Glucose concentrations of 0 to 500 mg dl^{-1} (27.8 mmol l^{-1}) could be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (21.7 kPa). Since the electrode is capable of operating where the oxygen concentration is low, it is thought to be suitable for implantation in subcutaneous tissue and may prove to be a key development in the realisation of a closed-loop artificial endocrine pancreas.

The Kusano publication, pg. 8.

The sensor system of the Kusano publication employs an air intake hole to draw ambient air into the sensor, and thus configures the system to measure current flow associated with the electrode, with substantial linearity, at glucose concentrations of about 400 mg/dL, even in a fluid with an oxygen concentration at 0 mg/L. See, the Kusano publication, MATERIALS section, pgs. 2-3, and FIGs. 2 and 8. The air intake hole described in the Kusano publication is a simple mechanical modification to a sensor, which provides ambient oxygen to the electroactive surface. One of ordinary skill in the art would understand how to modify the sensor of the Rhodes '874 publication to include the air intake hole of the Kusano publication, without undue experimentation and with reasonable expectation of success. Such modification does not change the chemistry, or general function of the sensor. Instead, such modification merely provides ambient oxygen to the sensor when the oxygen concentration within the fluid is inadequate for the function of the sensor. As such, the sensor of the Rhodes '874 publication can be combined with the air intake hole of the Kusano publication to measure glucose in a fluid with an oxygen concentration below 0.6 mg/L, as called for in claim 1. The sensor of claim 1 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 1 would have been obvious to one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication and the Kusano publication. Claim 1 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

2. Dependent Claim 2

In addition to showing each and every feature of claim 1, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 2, which depends from claim 1, and thus renders claim 2 obvious under 35 U.S.C. § 103(a).

> Claim 2. The glucose sensor system of claim 1, wherein the sensor electronics are configured to directly measure the current flow associated with the electrode.

The Rhodes '874 publication teaches sensor electronics configured to directly measure the current flow associated with the electrode. See, for example, the Rhodes '874 publication, pg. 9, [0113]-[0115].

3. Dependent Claim 4

In addition to showing each and every feature of claim 1, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 4, which depends from claim 1, and thus renders claim 4 obvious under 35 U.S.C. § 103(a).

> Claim 4. The glucose sensor system of claim 1, wherein the membrane comprises a resistance domain configured with a permeability ratio of at least about 50:1 co-analyte to glucose concentration.

The Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having desired ratios of diffusion. See, for example, the Rhodes '874 publication, pgs. 6, [0082] – pg. 7, [0084]. Specifically, the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "a permeability ratio of at least about 50:1 co-analyte to glucose concentration."

4. Dependent Claim 5

In addition to showing each and every feature of claim 4, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 5, which depends from claim 4, and thus renders claim 5 obvious under 35 U.S.C. § 103(a).

> Claim 5. The glucose sensor system of claim 4, wherein the permeability ratio is at least about 200:1.

The Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having desired ratios of diffusion. See, for example, the Rhodes '874 publication, pgs. 6, [0082] – pg. 7, [0084]. Specifically, the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "the permeability ratio is at least 200:1."

5. Dependent Claim 6

In addition to showing each and every feature of claim 1, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 6, which depends from claim 1, and thus renders claim 6 obvious under 35 U.S.C. § 103(a).

> Claim 6. The glucose sensor system of claim 1, wherein the membrane comprises an enzyme.

The sensor of the Rhodes '874 publication includes an enzyme configured to catalyze a reaction of glucose and oxygen. See, for example, the Rhodes '874 publication, pg. 7, [0086]-[0088].

The sensor of the Kusano publication includes an enzyme configured to catalyze a reaction of glucose and oxygen. See, for example, the Kusano publication, pgs. 1-3, and FIG 2.

6. Dependent Claim 7

In addition to showing each and every feature of claim 1, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 7, which depends from claim 1, and thus renders claim 7 obvious under 35 U.S.C. § 103(a).

> Claim 7. The glucose sensor system of claim 1, wherein the system is configured to determine a concentration of the glucose in a biological sample via measurement of hydrogen peroxide produced by an enzyme-catalyzed reaction of glucose with oxygen.

The Rhodes '874 publication teaches a sensor system configured to determine a concentration of the glucose in a biological sample via measurement of hydrogen peroxide produced by an enzyme-catalyzed reaction of glucose with oxygen. See, for example, the Rhodes '874 publication, FIG. 1; pg. 3, [0022], [0027]; and pg. 6, [0073].

7. Dependent Claim 8

In addition to showing each and every feature of claim 1, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 8, which depends from claim 1, and thus renders claim 8 obvious under 35 U.S.C. § 103(a).

> Claim 8. The glucose sensor system of claim 1, wherein the system is configured to have an operable life implanted within a host of at least about one week.

The Rhodes '874 publication teaches implantable glucose sensors employing multi-region membranes which have "enabled function of devices for over one year in vivo." The Rhodes '874 publication, pg. 5, [0061].

8. Dependent Claim 9

In addition to showing each and every feature of claim 1, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 9, which depends from claim 1, and thus renders claim 9 obvious under 35 U.S.C. § 103(a).

> Claim 9. The glucose sensor system of claim 1, wherein the system is configured to measure glucose with substantial linearity at an oxygen concentration of less than about 0.3mg/L.

The Rhodes '874 publication discloses that testing was conducted up to a glucose concentration of 400 mg/dL, with oxygen concentrations down to 0.1 mg/L. See, for example, the Rhodes '874 publication, EXAMPLE 2, pg. 10, [0131]-[0137]. In paragraph [0136], the Rhodes '874 publication states, "A glucose value was recorded for each device at decreasing oxygen concentrations from ambient to approximately 0.1 mg/L." As such, the Rhodes '874 publication discloses a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.3 mg/L, as called for in claim 9.

The sensor system of the Kusano publication employs an air intake hole to draw ambient air into the sensor, and thus configures the system to measure current flow associated with the electrode, with substantial linearity, at glucose concentrations of about 400 mg/dL, even in a fluid with an oxygen concentration at 0 mg/L. See, the Kusano publication, MATERIALS section, pgs. 2-3, and FIGs. 2 and 8. As discussed above, one of ordinary skill in the art would understand how to modify the sensor of the Rhodes '874 publication to include the air intake hole of the Kusano publication, and thus cure any deficiency in oxygen by drawing ambient oxygen into the sensor.. Such modification would allow for the sensor of the Rhodes '874 publication to measure glucose in a fluid with an oxygen concentration below 0.3 mg/L, as called for in claim 9. The sensor of claim 9 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 9 would have been obvious to one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication and the Kusano publication. Claim 1 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

9. Dependent Claim 11

In addition to showing each and every feature of claim 1, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 11, which depends from claim 1, and thus renders claim 11 obvious under 35 U.S.C. § 103(a).

> Claim 11. The glucose sensor system of claim 1, wherein the membrane comprises a polyurethane.

The Rhodes '874 publication teaches the membrane comprising a polyurethane. See, for example, the Rhodes '874 publication, pg. 5, [0070].

The Kusano publication teaches the membrane comprising a polyurethane. See the Kusano publication, pg. 6.

10. Independent Claim 12

> Claim 12. A glucose sensor system comprising:
>
> *Part of Claim 12*

The Rhodes '874 publication teaches a glucose sensor system. See the Rhodes '874 publication, Abstract; FIG. 1; and pg. 2, [0012]-[0017].

The Kusano publication teaches a glucose sensor system. See, for example, the Kusano publication, Abstract, and FIGs. 3, 4, and 9.

> an electrode configured to measure a concentration of glucose in a host;
>
> *Part of Claim 12*

The Rhodes '874 publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See, for example, the Rhodes '874 publication, Abstract; and pg. 2, [0012]-[0017] and [0020].

The Kusano publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See, for example, the Kusano publication pgs. 2-3, and FIG. 2.

> a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and
>
> *Part of Claim 12*

The Rhodes '874 publication teaches a multi-region membrane disposed over the electrode. See, for example, the Rhodes '874 publication, pg. 5, [0062] – pg. 8, [0108]; and FIGs. 2A-2F. The membrane includes a resistance domain configured to limit transport of glucose to the electrode. See, for example, pg. 6, [0082] – pg. 7, [0085].

The Kusano publication teaches a polyurethane membrane disposed over the electrode. See, for example, FIG. 2. The membrane includes a resistance domain configured to limit transport of glucose to the electrode. See, for example, the Kusano publication, pgs. 1-3.

> sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode;
>
> wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.6 mg/L, and wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL.
>
> *Part of Claim 12*

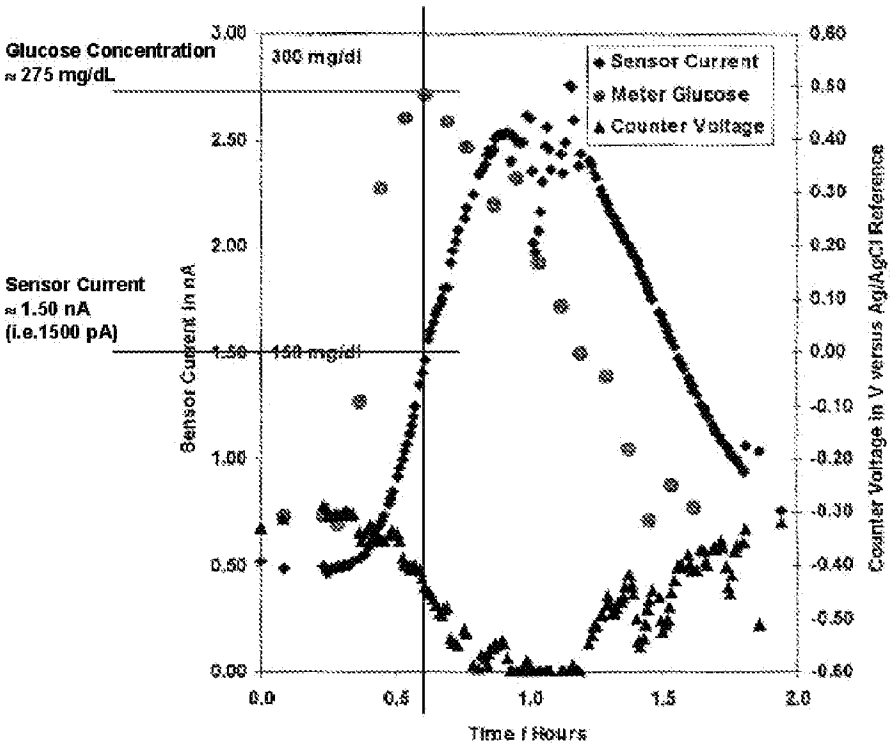
The Rhodes '874 publication teaches sensor electronics operably connected to the electrode and configured to measure a current flow associate with the electrode. See, for example, the Rhodes '874 publication, FIG. 3; pg. 8, [0107] – pg. 9, [0115].

Further, the Rhodes '874 publication teaches that the system is configured to measure the current flow associated with the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL, in a fluid with an oxygen concentration of less than about 0.6 mg/L. For example, the Rhodes '874 publication discloses that testing was conducted up to a glucose concentration of 400 mg/dL, with oxygen concentrations down to 0.1 mg/L. See, for example, the Rhodes '874 publication, EXAMPLE 2, pg. 10, [0131]-[0137]. In paragraph [0136], the Rhodes '874 publication states, "A glucose value was recorded for each device at decreasing oxygen concentrations from ambient to approximately 0.1 mg/L." In paragraph [0137], the Rhodes '874 publication states, "For example, at an oxygen concentration of about 0.5 mg/L, devices containing the silicone membrane are providing 100% output as compared to 80% output for the control devices." As such, the Rhodes '874 publication discloses a sensor system that

measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.6 mg/L, as called for in claim 12.

Finally, the Rhodes '874 publication teaches that the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 25 pA/mg/dL. For example, the Rhodes '874 publication discloses an implantable glucose sensor that showed no oxygen dependence to oxygen concentrations as low as 0.1 mg/L, and a sensitivity of at least 5.5 pA/mg/dL, to increasing concentrations up to 400 mg/dL of glucose. See, for example, the Rhodes '874 publication, FIGs. 3 and 9; and pg. 11, [0131]-[0141].

FIG. 3 of the Rhodes '874 publication (reproduced below and annotated for clarity) shows a sensor system configured to have a sensor output of at least 5.5 pA/mg/dL, between 0-300 mg/dL. For example, at a glucose concentration of 275 mg/dL, the glucose sensor system of the Rhodes '874 publication has a sensor current of 1.5 nA (i.e., 1,500 pA). Therefore, the Rhodes '874 publication discloses a glucose sensor system that has a sensitivity of at least 5.5 pA/mg/dL. As such, the disclosed sensor sensitivity of at least 5.5 pA/mg/dL in the Rhodes '874 publication falls within the claimed range of about 1 pA/mg/dL to about 25 pA/mg/dL.



The Kusano publication teaches sensor electronics operably connected to the electrode. The sensor electronics measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL, in a fluid with an oxygen concentration of less than about 0.3 mg/L. Specifically, the Kusano publication states, "The glucose electrode with percutaneous interface described in this paper differs from [previously described electrodes] using a novel approach to overcome the lack of oxygen in the interstitial fluid." *Id.* The Kusano publication further states:

> The electrode has a linear response to glucose concentration at an electrode output current ranging from 0 to 20nA ***even when the oxygen concentration of the glucose solution is zero***. The use of polyurethane as a diffusion barrier to glucose limits the electrode output current at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) to 20 nA. Therefore, the electrode can measure glucose concentrations up to 500 mg dl^{-1} (27.8 mmol l^{-1}) ***with no oxygen*** dissolved in the glucose solution.

The Kusano publication, Abstract (emphasis added).

Figure 8 of the Kusano publication (reproduced below) shows a linear current measurement up to 500 mg/dL, even at 0 kPa of P_{O_2}.

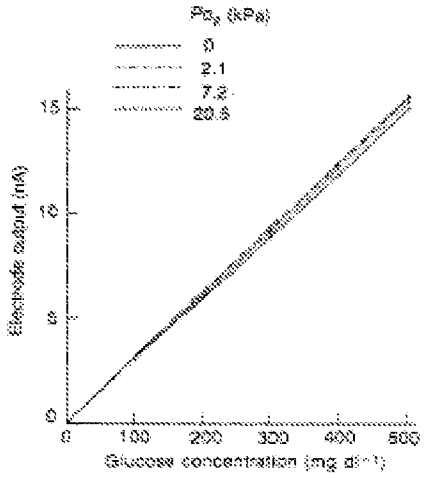


Figure 8. Electrode calibration curves under various P_{O_2}.

The concluding remarks of the Kusano publication further state:

> Glucose concentrations of 0 to 500 mg dl^{-1} (27.8 mmol l^{-1}) could be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (21.7 kPa). Since the electrode is capable of operating where the oxygen concentration is low, it is thought to be suitable for implantation in subcutaneous tissue and may prove

> to be a key development in the realisation of a closed-loop artificial endocrine pancreas.

The Kusano publication, pg. 8.

The sensor system of the Kusano publication employs an air intake hole to draw ambient air into the sensor, and thus configures the system to measure current flow associated with the electrode, with substantial linearity, at glucose concentrations of about 400 mg/dL, even in a fluid with an oxygen concentration at 0 mg/L. See, the Kusano publication, MATERIALS section, pgs. 2-3, and FIGs. 2 and 8. The air intake hole described in the Kusano publication is a simple mechanical modification to a sensor, which provides ambient oxygen to the electroactive surface. One of ordinary skill in the art would understand how to modify the sensor of the Rhodes '874 publication to include the air intake hole of the Kusano publication, without undue experimentation and with reasonable expectation of success. Such modification does not change the chemistry, or general function of the sensor. Instead, such modification merely provides ambient oxygen to the sensor when the oxygen concentration within the fluid is inadequate for the function of the sensor. As such, the sensor of the Rhodes '874 publication can be combined with the air intake hole of the Kusano publication to measure glucose in a fluid with an oxygen concentration below 0.6 mg/L, as called for in claim 12. The sensor of claim 12 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 18 would have been obvious to one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication and the Kusano publication. Claim 12 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

11. Dependent Claim 13

In addition to showing each and every feature of claim 12, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 13, which depends from claim 12, and thus renders claim 13 obvious under 35 U.S.C. § 103(a).

> Claim 13. The glucose sensor system of claim 12, wherein the electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2.

The Rhodes '874 publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See, for example, the Rhodes '874 publication , Abstract; and pg. 2, [0012]-[0017] and [0020]. The electrode comprises an exposed electroactive

surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2. See, for example, the Rhodes '874 publication, pg. 3, [0022]; and pgs. 8-9, [0110]-[0112]. More specifically, the Rhodes '874 publication describes the use of a wire electrode with a modified reactive surface. *See Id.* at [0112]. The diameter of the wire is 0.0508 cm (0.020"). *Id.* A wire diameter of 0.0508 cm results in an unmodified reactive surface area of 0.002 cm^2 ($SA_{unmodified} = \pi r^2$). Accordingly, the 0.002 cm^2 surface area of the Rhodes '874 publication falls within the range of 0.000084 cm^2 to about 0.016 cm^2.

Moreover, the Rhodes '874 publication also discloses modifying the wire electrode to resemble a "T" configuration at the end of the electrode, thereby changing the electrochemically reactive surface area depending on the size of the "T". *Id.* at [0110]. Therefore, the resulting modified electrode can be 2-10, 2-25, 2-50, or 2-100 times the surface area of the unmodified wire electrode. *Id.* at [0110]. As such, the Rhodes '874 publication teaches electrodes with electroactive surfaces with areas ranging from about 0.004 cm^2 to about 0.02 cm^2, which fall within the claimed range, and thus anticipates the claimed limitation.

The Kusano publication teaches an electroactive surface area that falls within the range of 0.000084 cm^2 to about 0.016 cm^2. Specifically, the Kusano publication teaches a working electrode with "0.5 μg of albumin-linked glucose oxidase [] immobilised at the tip" of a "Pt wire 0.5 mm in diameter." See the Kusano publication, Abstract. The surface area of the electroactive surface is therefore the surface area of the tip of the Pt wire, which is equal to 0.00196 cm^2 (Area = πr^2 = (3.14)(0.25mm)^2 = 0.196 mm^2 = 0.00196 cm^2). A surface area of 0.00196 cm^2 falls within the claimed range of about 0.000084 cm^2 to about 0.016 cm^2.

12. Dependent Claim 14

In addition to showing each and every feature of claim 12, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 14, which depends from claim 12, and thus renders claim 14 obvious under 35 U.S.C. § 103(a).

> Claim 14. The glucose sensor system of claim 12, wherein the membrane comprises a resistance domain configured with a permeability ratio of at least about 50:1 co-analyte to glucose concentration.

The Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having desired ratios of diffusion. See, for example, the Rhodes '874

publication, pgs. 6, [0082] – pg. 7, [0084]. Specifically, the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "a permeability ratio of at least about 50:1 co-analyte to glucose concentration."

13. Dependent Claim 15

In addition to showing each and every feature of claim 14, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 15, which depends from claim 14, and thus renders claim 15 obvious under 35 U.S.C. § 103(a).

> Claim 15. The glucose sensor system of claim 14, wherein the permeability ratio is at least about 200:1.

The Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having desired ratios of diffusion. See, for example, the Rhodes '874 publication, pgs. 6, [0082] – pg. 7, [0084]. Specifically, the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "the permeability ratio is at least about 200:1."

14. Dependent Claim 16

In addition to showing each and every feature of claim 12, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 16, which depends from claim 12, and thus renders claim 16 obvious under 35 U.S.C. § 103(a).

> Claim 16. The glucose sensor system of claim 12, wherein the membrane comprises an enzyme.

The sensor of the Rhodes '874 publication includes an enzyme configured to catalyze a reaction of glucose and oxygen. See, for example, the Rhodes '874 publication, pg. 7, [0086]-[0088].

The sensor of the Kusano publication includes an enzyme configured to catalyze a reaction of glucose and oxygen. See, for example, the Kusano publication, pgs. 1-3, and FIG 2.

15. Dependent Claim 17

In addition to showing each and every feature of claim 12, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 17, which depends from claim 12, and thus renders claim 17 obvious under 35 U.S.C. § 103(a).

> Claim 17. The glucose sensor system of claim 12, wherein the glucose sensitivity is from about 1 pA/mg/dL to about 10 pA/mg/dL.

The Rhodes '874 publication discloses a sensor system configured to have a sensor output of at least 5.5 pA/mg/dL between 0-300 mg/dL. As such, the disclosed sensor sensitivity of at least 5.5 pA/mg/dL in the Rhodes '874 publication falls within the claimed range of about 1 pA/mg/dL to about 10 pA/mg/dL.

16. Dependent Claim 18

In addition to showing each and every feature of claim 12, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 18, which depends from claim 12, and thus renders claim 18 obvious under 35 U.S.C. § 103(a).

> Claim 18. The glucose sensor system of claim 12, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.15 mg/L.

The Rhodes '874 publication discloses that testing was conducted up to a glucose concentration of 400 mg/dL, with oxygen concentrations down to 0.1 mg/L. See, for example, the Rhodes '874 publication, EXAMPLE 2, pg. 10, [0131]-[0137]. In paragraph [0136], the Rhodes '874 publication states, "A glucose value was recorded for each device at decreasing oxygen concentrations from ambient to approximately 0.1 mg/L." As such, the Rhodes '874 publication discloses a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.15 mg/L, as called for in claim 18.

As discussed above, the Kusano publication teaches a sensor configured to measure glucose concentrations "even when the oxygen concentration of the glucose solution is zero." The Kusano publication, Abstract. As such, the Kusano publication meets the claim limitation of the oxygen concentration being less than about 0.15 mg/L. The sensor system of the Kusano publication employs an air intake hole to draw ambient air into the sensor, and thus configures

the system to measure current flow associated with the electrode, with substantial linearity, at glucose concentrations of about 400 mg/dL, even in a fluid with an oxygen concentration at 0 mg/L. See, the Kusano publication, MATERIALS section, pgs. 2-3, and FIGs. 2 and 8. One of ordinary skill in the art would understand how to modify the sensor of the Rhodes '874 publication to include the air intake hole of the Kusano publication, and thus cure any oxygen deficiency by drawing in ambient oxygen to the sensor. Such modification would allow for the sensor of the Rhodes '874 publication to measure glucose in a fluid with an oxygen concentration below 0.15 mg/L, as called for in claim 18. The sensor of claim 18 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 18 would have been obvious to one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication and the Kusano publication. Claim 18 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

17. Dependent Claim 19

In addition to showing each and every feature of claim 12, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 19, which depends from claim 12, and thus renders claim 19 obvious under 35 U.S.C. § 103(a).

> Claim 19. The glucose sensor system of claim 12, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.05 mg/L.

As discussed above, the sensor system of the Kusano publication employs an air intake hole to draw ambient air into the sensor, and thus configures the system to measure current flow associated with the electrode, with substantial linearity, at glucose concentrations of about 400 mg/dL, even in a fluid with an oxygen concentration at 0 mg/L. See, the Kusano publication, MATERIALS section, pgs. 2-3, and FIGs. 2 and 8. One of ordinary skill in the art would understand how to modify the sensor of the Rhodes '874 publication to include the air intake hole of the Kusano publication, and thus cure any oxygen deficiency by drawing in ambient oxygen to the sensor. Such modification would allow for the sensor of the Rhodes '874 publication to measure glucose in a fluid with an oxygen concentration below 0.05 mg/L, as called for in claim 19. The sensor of claim 19 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 19 would have been obvious to

one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication and the Kusano publication. Claim 19 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

18. Dependent Claim 20

In addition to showing each and every feature of claim 12, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 20, which depends from claim 12, and thus renders claim 20 obvious under 35 U.S.C. § 103(a).

Claim 20 The glucose sensor system of claim 12, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.02 mg/L.

As discussed above, the sensor system of the Kusano publication employs an air intake hole to draw ambient air into the sensor, and thus configures the system to measure current flow associated with the electrode, with substantial linearity, at glucose concentrations of about 400 mg/dL, even in a fluid with an oxygen concentration at 0 mg/L. See, the Kusano publication, MATERIALS section, pgs. 2-3, and FIGs. 2 and 8. One of ordinary skill in the art would understand how to modify the sensor of the Rhodes '874 publication to include the air intake hole of the Kusano publication, and thus cure any oxygen deficiency by drawing in ambient oxygen to the sensor. Such modification would allow for the sensor of the Rhodes '874 publication to measure glucose in a fluid with an oxygen concentration below 0.02 mg/L, as called for in claim 20. The sensor of claim 20 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 20 would have been obvious to one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication and the Kusano publication. Claim 20 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007)..

19. Dependent Claim 21

In addition to showing each and every feature of claim 12, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 21, which depends from claim 12, and thus renders claim 21 obvious under 35 U.S.C. § 103(a).

> Claim 21 The glucose sensor system of claim 12, wherein the sensor electronics are configured to directly measure the current flow associated with the electrode.

The Rhodes '874 publication teaches sensor electronics configured to directly measure the current flow associated with the electrode. See, for example, the Rhodes '874 publication, pg. 9, [0113]-[0115].

20. Dependent Claim 23

In addition to showing each and every feature of claim 12, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 23, which depends from claim 12, and thus renders claim 23 obvious under 35 U.S.C. § 103(a).

> Claim 23. The glucose sensor system of claim 12, wherein the system is configured to determine a concentration of glucose in a biological sample via measurement of hydrogen peroxide produced by an enzyme-catalyzed reaction of glucose with oxygen.

The Rhodes '874 publication teaches a sensor system configured to determine a concentration of the glucose in a biological sample via measurement of hydrogen peroxide produced by an enzyme-catalyzed reaction of glucose with oxygen. See, for example, the Rhodes '874 publication, FIG. 1; pg. 3, [0022], [0027]; and pg. 6, [0073].

21. Dependent Claim 24

In addition to showing each and every feature of claim 12, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 24, which depends from claim 12, and thus renders claim 24 obvious under 35 U.S.C. § 103(a).

> Claim 24. The glucose sensor system of claim 12, wherein the system is configured to have an operable life implanted within a host of at least about one week.

The Rhodes '874 publication teaches implantable glucose sensors employing multi-region membranes which have "enabled function of devices for over one year in vivo." The Rhodes '874 publication, pg. 5, [0061].

22. Dependent Claim 25

In addition to showing each and every feature of claim 12, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 25, which depends from claim 12, and thus renders claim 25 obvious under 35 U.S.C. § 103(a).

> Claim 25. The glucose sensor system of claim 12, wherein the system is configured to measure glucose with substantial linearity at an oxygen concentration of less than about 0.3mg/L.

The Rhodes '874 publication discloses that testing was conducted up to a glucose concentration of 400 mg/dL, with oxygen concentrations down to 0.1 mg/L. See, for example, the Rhodes '874 publication, EXAMPLE 2, pg. 10, [0131]-[0137]. In paragraph [0136], the Rhodes '874 publication states, "A glucose value was recorded for each device at decreasing oxygen concentrations from ambient to approximately 0.1 mg/L." As such, the Rhodes '874 publication discloses a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.3 mg/L, as called for in claim 25.

The sensor system of the Kusano publication employs an air intake hole to draw ambient air into the sensor, and thus configures the system to measure current flow associated with the electrode, with substantial linearity, at glucose concentrations of about 400 mg/dL, even in a fluid with an oxygen concentration at 0 mg/L. See, the Kusano publication, MATERIALS section, pgs. 2-3, and FIGs. 2 and 8. As discussed above, one of ordinary skill in the art would understand how to modify the sensor of the Rhodes '874 publication to include the air intake hole of the Kusano publication, and thus cure any oxygen deficiency by drawing in ambient oxygen to the sensor. Such modification would allow for the sensor of the Rhodes '874 publication to measure glucose in a fluid with an oxygen concentration below 0.3 mg/L, as called for in claim 25. The sensor of claim 25 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 25 would have been obvious to one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication and the Kusano publication. Claim 25 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

23. Dependent Claim 27

In addition to showing each and every feature of claim 12, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 27, which depends from claim 12, and thus renders claim 27 obvious under 35 U.S.C. § 103(a).

> Claim 27. The glucose sensor system of claim 12, wherein the membrane comprises a polyurethane.

The Rhodes '874 publication teaches the membrane comprising a polyurethane. See, for example, the Rhodes '874 publication, pg. 5, [0070].

The Kusano publication teaches the membrane comprising a polyurethane. See the Kusano publication, pg. 6.

24. Independent Claim 28

> Claim 28. A glucose sensor system comprising:
>
> *Part of Claim 28*

The Rhodes '874 publication teaches a glucose sensor system. See the Rhodes '874 publication, Abstract; FIG. 1; and pg. 2, [0012]-[0017].

The Kusano publication teaches a glucose sensor system. See, for example, the Kusano publication, Abstract, and FIGs. 3, 4, and 9.

> an electrode configured to measure a concentration of glucose in a host;
>
> *Part of Claim 28*

The Rhodes '874 publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See, for example, the Rhodes '874 publication, Abstract; and pg. 2, [0012]-[0017] and [0020].

The Kusano publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See, for example, the Kusano publication pgs. 2-3, and FIG.

> a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and
>
> *Part of Claim 28*

The Rhodes '874 publication teaches a multi-region membrane disposed over the electrode. See, for example, the Rhodes '874 publication, pg. 5, [0062] – pg. 8, [0108]; and FIGs. 2A-2F. The membrane includes a resistance domain configured to limit transport of glucose to the electrode. See, for example, pg. 6, [0082] – pg. 7, [0085].

The Kusano publication teaches a polyurethane membrane disposed over the electrode. See, for example, FIG. 2. The membrane includes a resistance domain configured to limit transport of glucose to the electrode. See, for example, the Kusano publication, pgs. 1-3.

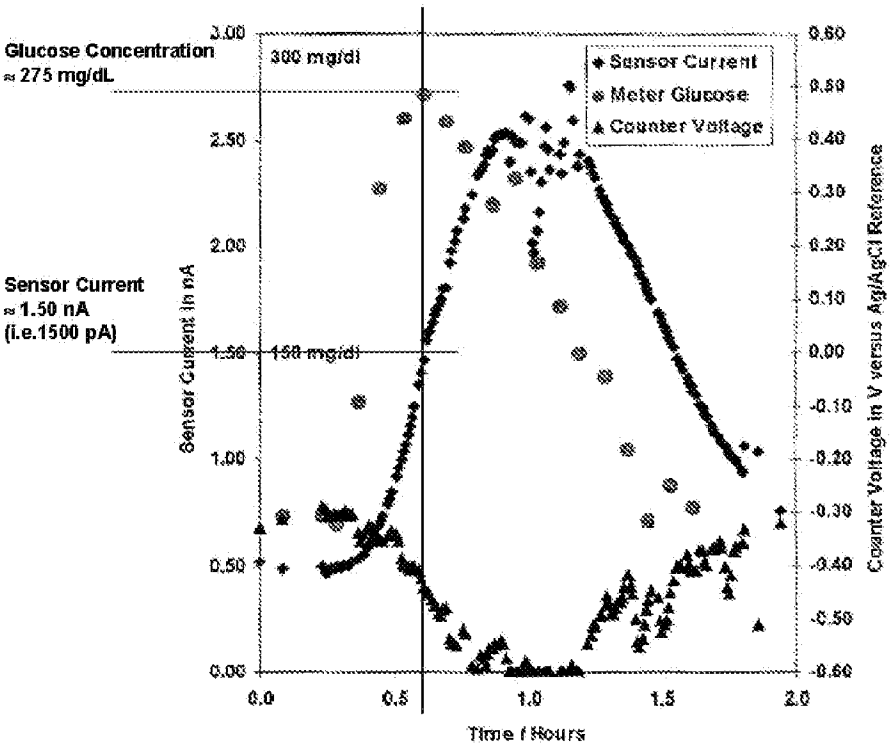
> sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode;
>
> wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL, and wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L.
>
> *Part of Claim 28*

The Rhodes '874 publication teaches sensor electronics operably connected to the electrode and configured to measure a current flow associate with the electrode. See, for example, the Rhodes '874 publication, FIG. 3; pg. 8, [0107] – pg. 9, [0115].

Further, the Rhodes '874 publication teaches that the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL. For example, the Rhodes '874 publication discloses an implantable glucose sensor that showed no oxygen dependence to oxygen concentrations as low as 0.1 mg/L, and a sensitivity of at least 5.5 pA/mg/dL, to increasing concentrations up to 400 mg/dL of glucose. See, for example, the Rhodes '874 publication, FIGs. 3 and 9; and pg. 11, [0131]-[0141].

FIG. 3 of the Rhodes '874 publication (reproduced below and annotated for clarity) shows a sensor system configured to have a sensor output of at least 5.5 pA/mg/dL, between 0-300 mg/dL. For example, at a glucose concentration of 275 mg/dL, the glucose sensor system of the Rhodes '874 publication has a sensor current of 1.5 nA (i.e., 1,500 pA). Therefore, the Rhodes '874 publication discloses a glucose sensor system that has a sensitivity of at least 5.5

pA/mg/dL. As such, the disclosed sensor sensitivity of at least 5.5 pA/mg/dL in the Rhodes '874 publication falls within the claimed range of about 1 pA/mg/dL to about 100 pA/mg/dL.



Finally, the Rhodes '874 publication discloses that testing was conducted up to a glucose concentration of 400 mg/dL, with oxygen concentrations down to 0.1 mg/L. See, for example, the Rhodes '874 publication, EXAMPLE 2, pg. 10, [0131]-[0137]. In paragraph [0136], the Rhodes '874 publication states, "A glucose value was recorded for each device at decreasing oxygen concentrations from ambient to approximately 0.1 mg/L." As such, the Rhodes '874 publication discloses a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.3 mg/L, as called for in claim 28.

The Kusano publication teaches sensor electronics operably connected to the electrode. The sensor electronics measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL, in a fluid with an oxygen concentration of less than about 0.3 mg/L. Specifically, the Kusano publication states, "The glucose electrode with percutaneous interface described in this paper differs from [previously described electrodes]

using a novel approach to overcome the lack of oxygen in the interstitial fluid." *Id.* The Kusano publication further states:

> The electrode has a linear response to glucose concentration at an electrode output current ranging from 0 to 20nA ***even when the oxygen concentration of the glucose solution is zero***. The use of polyurethane as a diffusion barrier to glucose limits the electrode output current at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) to 20 nA. Therefore, the electrode can measure glucose concentrations up to 500 mg dl^{-1} (27.8 mmol l^{-1}) ***with no oxygen*** dissolved in the glucose solution.

The Kusano publication, Abstract (emphasis added).

Figure 8 of the Kusano publication (reproduced below) shows a linear current measurement up to 500 mg/dL, even at 0 kPa of Po_2.

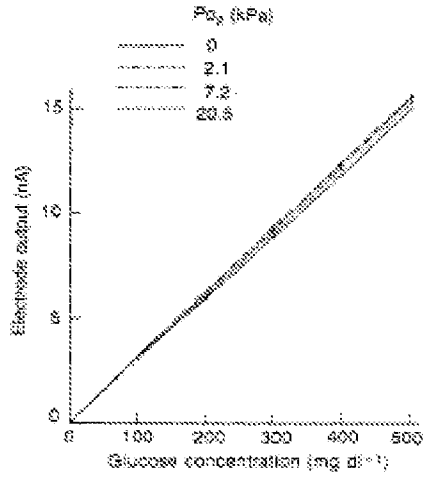


Figure 8. Electrode calibration curves under various Po_2.

The concluding remarks of the Kusano publication further state:

> Glucose concentrations of 0 to 500 mg dl^{-1} (27.8 mmol l^{-1}) could be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (21.7 kPa). Since the electrode is capable of operating where the oxygen concentration is low, it is thought to be suitable for implantation in subcutaneous tissue and may prove to be a key development in the realisation of a closed-loop artificial endocrine pancreas.

The Kusano publication, pg. 8.

The Kusano publication states, "In addition, the steady state current at a glucose concentration of 500 mg/dL (27.8 mmol/L) should be less than the saturation current which

results when the oxygen supplied from the air is limited, which is about 20 nA in this electrode." The Kusano publication, pg. 6. As such, the Kusano publication teaches a sensitivity of less than 40 pA/mg/dL (i.e., 20,000 pA divided by 500 mg/dL).

The sensor system of the Kusano publication employs an air intake hole to draw ambient air into the sensor, and thus configures the system to measure current flow associated with the electrode, with substantial linearity, at glucose concentrations of about 400 mg/dL, even in a fluid with an oxygen concentration at 0 mg/L. See, the Kusano publication, MATERIALS section, pgs. 2-3, and FIGs. 2 and 8. The air intake hole described in the Kusano publication is a simple mechanical modification to a sensor, which provides ambient oxygen to the electroactive surface. One of ordinary skill in the art would understand how to modify the sensor of the Rhodes '874 publication to include the air intake hole of the Kusano publication, without undue experimentation and with reasonable expectation of success. Such modification does not change the chemistry, or general function of the sensor. Instead, such modification merely provides ambient oxygen to the sensor when the oxygen concentration within the fluid is inadequate for the function of the sensor. As such, the sensor of the Rhodes '874 publication can be combined with the air intake hole of the Kusano publication to measure glucose in a fluid with an oxygen concentration below 0.3 mg/L, as called for in claim 28. The sensor of claim 28 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 28 would have been obvious to one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication and the Kusano publication. Claim 28 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

25. Dependent Claim 29

In addition to showing each and every feature of claim 28, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 29, which depends from claim 28, and thus renders claim 29 obvious under 35 U.S.C. § 103(a).

> Claim 29. The glucose sensor system of claim 28, wherein the electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2.

The Rhodes '874 publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See, for example, the Rhodes '874 publication ,

Abstract; and pg. 2, [0012]-[0017] and [0020]. The electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2. See, for example, the Rhodes '874 publication, pg. 3, [0022]; and pgs. 8-9, [0110]-[0112]. More specifically, the Rhodes '874 publication describes the use of a wire electrode with a modified reactive surface. *See Id.* at [0112]. The diameter of the wire is 0.0508 cm (0.020"). *Id.* A wire diameter of 0.0508 cm results in an unmodified reactive surface area of 0.002 cm^2 ($SA_{unmodified} = \pi r^2$). Accordingly, the 0.002 cm^2 surface area of the Rhodes '874 publication falls within the range of 0.000084 cm^2 to about 0.016 cm^2.

Moreover, the Rhodes '874 publication also discloses modifying the wire electrode to resemble a "T" configuration at the end of the electrode, thereby changing the electrochemically reactive surface area depending on the size of the "T". *Id.* at [0110]. Therefore, the resulting modified electrode can be 2-10, 2-25, 2-50, or 2-100 times the surface area of the unmodified wire electrode. *Id.* at [0110]. As such, the Rhodes '874 publication teaches electrodes with electroactive surfaces with areas ranging from about 0.004 cm^2 to about 0.02 cm^2, which fall within the claimed range, and thus anticipates the claimed limitation.

The Kusano publication teaches an electroactive surface area that falls within the range of 0.000084 cm^2 to about 0.016 cm^2. Specifically, the Kusano publication teaches a working electrode with "0.5 μg of albumin-linked glucose oxidase [] immobilised at the tip" of a "Pt wire 0.5 mm in diameter." See the Kusano publication, Abstract. The surface area of the electroactive surface is therefore the surface area of the tip of the Pt wire, which is equal to 0.00196 cm^2 (Area = πr^2 = (3.14)(0.25mm)^2 = 0.196 mm^2 = 0.00196 cm^2). A surface area of 0.00196 cm^2 falls within the claimed range of about 0.000084 cm^2 to about 0.016 cm^2.

26. Dependent Claim 30

In addition to showing each and every feature of claim 28, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 30, which depends from claim 28, and thus renders claim 30 obvious under 35 U.S.C. § 103(a).

> Claim 30. The glucose sensor system of claim 28, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.15 mg/L.

The Rhodes '874 publication discloses that testing was conducted up to a glucose concentration of 400 mg/dL, with oxygen concentrations down to 0.1 mg/L. See, for example, the Rhodes '874 publication, EXAMPLE 2, pg. 10, [0131]-[0137]. In paragraph [0136], the Rhodes '874 publication states, "A glucose value was recorded for each device at decreasing oxygen concentrations from ambient to approximately 0.1 mg/L." As such, the Rhodes '874 publication discloses a sensor system that measures glucose concentrations in a fluid with an oxygen concentration of less than about 0.15 mg/L, as called for in claim 30.

As discussed above, the Kusano publication teaches a sensor configured to measure glucose concentrations "even when the oxygen concentration of the glucose solution is zero." The Kusano publication, Abstract. As such, the Kusano publication meets the claim limitation of the oxygen concentration being less than about 0.15 mg/L. The sensor system of the Kusano publication employs an air intake hole to draw ambient air into the sensor, and thus configures the system to measure current flow associated with the electrode, with substantial linearity, at glucose concentrations of about 400 mg/dL, even in a fluid with an oxygen concentration at 0 mg/L. See, the Kusano publication, MATERIALS section, pgs. 2-3, and FIGs. 2 and 8. One of ordinary skill in the art would understand how to modify the sensor of the Rhodes '874 publication to include the air intake hole of the Kusano publication, and thus cure any oxygen deficiency by drawing in ambient oxygen to the sensor. Such modification would allow for the sensor of the Rhodes '874 publication to measure glucose in a fluid with an oxygen concentration below 0.15 mg/L, as called for in claim 30. The sensor of claim 30 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 30 would have been obvious to one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication and the Kusano publication. Claim 30 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

27. Dependent Claim 31

In addition to showing each and every feature of claim 28, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 31, which depends from claim 28, and thus renders claim 31 obvious under 35 U.S.C. § 103(a).

> Claim 31. The glucose sensor system of claim 28, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.05 mg/L.

As discussed above, the sensor system of the Kusano publication employs an air intake hole to draw ambient air into the sensor, and thus configures the system to measure current flow associated with the electrode, with substantial linearity, at glucose concentrations of about 400 mg/dL, even in a fluid with an oxygen concentration at 0 mg/L. See, the Kusano publication, MATERIALS section, pgs. 2-3, and FIGs. 2 and 8. One of ordinary skill in the art would understand how to modify the sensor of the Rhodes '874 publication to include the air intake hole of the Kusano publication, and thus cure any oxygen deficiency by drawing in ambient oxygen to the sensor. Such modification would allow for the sensor of the Rhodes '874 publication to measure glucose in a fluid with an oxygen concentration below 0.05 mg/L, as called for in claim 31. The sensor of claim 31 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 31 would have been obvious to one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication and the Kusano publication. Claim 31 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

28. Dependent Claim 32

In addition to showing each and every feature of claim 28, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 32, which depends from claim 28, and thus renders claim 32 obvious under 35 U.S.C. § 103(a).

> Claim 32. The glucose sensor system of claim 28, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.02 mg/L.

The sensor system of the Kusano publication employs an air intake hole to draw ambient air into the sensor, and thus configures the system to measure current flow associated with the electrode, with substantial linearity, at glucose concentrations of about 400 mg/dL, even in a fluid with an oxygen concentration at 0 mg/L. See, the Kusano publication, MATERIALS section, pgs. 2-3, and FIGs. 2 and 8. One of ordinary skill in the art would understand how to modify the sensor of the Rhodes '874 publication to include the air intake hole of the Kusano publication, and thus cure any oxygen deficiency by drawing in ambient oxygen. Such modification would allow for the sensor of the Rhodes '874 publication to measure glucose in a fluid with an oxygen concentration below 0.02 mg/L, as called for in claim 32. The sensor of claim 32 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 32 would have been obvious to one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication and the Kusano publication. Claim 12 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

29. Dependent Claim 33

In addition to showing each and every feature of claim 28, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 33, which depends from claim 28, and thus renders claim 33 obvious under 35 U.S.C. § 103(a).

> Claim 33. The glucose sensor system of claim 28, wherein the sensor electronics are configured to directly measure the current flow associated with the electrode.

The Rhodes '874 publication teaches sensor electronics configured to directly measure the current flow associated with the electrode. See, for example, the Rhodes '874 publication, pg. 9, [0113]-[0115].

30. Dependent Claim 35

In addition to showing each and every feature of claim 28, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 35, which depends from claim 28, and thus renders claim 35 obvious under 35 U.S.C. § 103(a).

> Claim 35. The glucose sensor system of claim 28, wherein the membrane comprises a resistance domain configured with a permeability ratio of at least about 50:1 co-analyte to glucose concentration.

The Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having desired ratios of diffusion. See, for example, the Rhodes '874 publication, pgs. 6, [0082] – pg. 7, [0084]. Specifically, the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "a permeability ratio of at least about 50:1 co-analyte to glucose concentration."

31. Dependent Claim 36

In addition to showing each and every feature of claim 35, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 36, which depends from claim 35, and thus renders claim 36 obvious under 35 U.S.C. § 103(a).

> Claim 36. The glucose sensor system of claim 35, wherein the permeability ratio is at least about 200:1.

The Rhodes '874 publication teaches that the multi-region membrane system can include a resistance domain having desired ratios of diffusion. See, for example, the Rhodes '874 publication, pgs. 6, [0082] – pg. 7, [0084]. Specifically, the Rhodes '874 publication teaches "oxygen-to-glucose permeability ratios of approximately 200:1." *Id.* As such, the Rhodes '874 publication meets the claim limitation of "the permeability ratio is at least about 200:1."

32. Dependent Claim 37

In addition to showing each and every feature of claim 28, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 37, which depends from claim 28, and thus renders claim 37 obvious under 35 U.S.C. § 103(a).

> Claim 37. The glucose sensor system of claim 28, wherein the membrane comprises an enzyme.

The sensor of the Rhodes '874 publication includes an enzyme configured to catalyze a reaction of glucose and oxygen. See, for example, the Rhodes '874 publication, pg. 7, [0086]-[0088].

The sensor of the Kusano publication includes an enzyme configured to catalyze a reaction of glucose and oxygen. See, for example, the Kusano publication, pgs. 1-3, and FIG 2.

33. Dependent Claim 38

In addition to showing each and every feature of claim 28, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 38, which depends from claim 28, and thus renders claim 38 obvious under 35 U.S.C. § 103(a).

> Claim 38. The glucose sensor system of claim 28, wherein the system is configured to determine a concentration of glucose in a biological sample via measurement of hydrogen peroxide produced by an enzyme-catalyzed reaction of glucose with oxygen.

The Rhodes '874 publication teaches a sensor system configured to determine a concentration of the glucose in a biological sample via measurement of hydrogen peroxide produced by an enzyme-catalyzed reaction of glucose with oxygen. See, for example, the Rhodes '874 publication, FIG. 1; pg. 3, [0022], [0027]; and pg. 6, [0073].

34. Dependent Claim 39

In addition to showing each and every feature of claim 28, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 39, which depends from claim 28, and thus renders claim 39 obvious under 35 U.S.C. § 103(a).

> Claim 39. The glucose sensor system of claim 28, wherein the system is configured to have an operable life implanted within a host of at least about one week.

The Rhodes '874 publication teaches implantable glucose sensors employing multi-region membranes which have "enabled function of devices for over one year in vivo." The Rhodes '874 publication, pg. 5, [0061].

35. Dependent Claim 41

In addition to showing each and every feature of claim 28, the combination of the Rhodes '874 publication and the Kusano publication discloses the features of claim 41, which depends from claim 28, and thus renders claim 41 obvious under 35 U.S.C. § 103(a).

> Claim 41. The glucose sensor system of claim 28, wherein the membrane comprises a polyurethane.

The Rhodes '874 publication teaches the membrane comprising a polyurethane. See, for example, the Rhodes '874 publication, pg. 5, [0070].

The Kusano publication teaches the membrane comprising a polyurethane. See the Kusano publication, pg. 6.

E. Claims 3, 22, and 34 are obvious under 35 U.S.C. § 103 in view of the Rhodes '874 publication, the Kusano publication, and the Jung '472 publication.

Claims 3, 22, and 34 are unpatentable under 35 U.S.C. § 103(a) over the Rhodes '874 publication in view of the Kusano publication, and further in view of the Jung '472 publication. Sections VI.E.1 – VI.E.3 detail how claims 3, 22, and 34 are rendered obvious by the teachings of the Rhodes '874 publication, the Kusano publication, and the Jung '472 publication. For the examiner's convenience, the arguments presented below are summarized in the table provided in **Exhibit M**.

1. Dependent Claim 3

As outlined above, the combination of the Rhodes '874 publication and the Kusano publication teaches each and every feature of claim 1. The combination of the Rhodes '874 publication, the Kusano publication, and the Jung '472 publication discloses the features of claim 3, which depends from claim 1. As such, claim 3 is unpatentable under 35 U.S.C. § 103(a).

> Claim 3. The glucose sensor system of claim 1, further comprising an analog-to-digital converter configured to translate the current flow measurement to a digital signal.

While the Rhodes '874 publication does not explicitly state that the sensor electronics use an analog-to-digital converter, the Jung '472 publication shows how an analog-to-digital converter can be used in a glucose sensor to translate the current flow measurement to a digital signal. See, for example, the Jung '472 publication, [0034]-[0035]. One of skill in the art would

understand that in order to convert the current flow from an analog signal to a digital signal, an analog-to-digital converter is necessary. In accordance with the teachings of the Jung '472 publication, one of skill in the art would recognize how to use an analog-to-digital converter in the sensor electronics of the Rhodes '874 publication. The sensor of claim 3 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 3 would have been obvious to one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication, the Kusano publication, and the Jung '472 publication. Claim 3 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

2. Dependent Claim 22

As outlined above, the combination of the Rhodes '874 publication and the Kusano publication teaches each and every feature of claim 12. The combination of the Rhodes '874 publication, the Kusano publication, and the Jung '472 publication discloses the features of claim 22, which depends from claim 12. As such, claim 22 is unpatentable under 35 U.S.C. § 103(a).

> Claim 22. The glucose sensor system of claim 12, further comprising an analog-to-digital converter configured to translate the current flow measurement to a digital signal.

While the Rhodes '874 publication does not explicitly state that the sensor electronics use an analog-to-digital converter, the Jung '472 publication shows how an analog-to-digital converter can be used in a glucose sensor to translate the current flow measurement to a digital signal. See, for example, the Jung '472 publication, [0034]-[0035]. One of skill in the art would understand that in order to convert the current flow from an analog signal to a digital signal, an analog-to-digital converter is necessary. In accordance with the teachings of the Jung '472 publication, one of skill in the art would recognize how to use an analog-to-digital converter in the sensor electronics of the Rhodes '874 publication. The sensor of claim 22 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 22 would have been obvious to one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication, the Kusano publication, and the Jung '472 publication. Claim 22 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

3. Dependent Claim 34

As outlined above, the combination of the Rhodes '874 publication and the Kusano publication teaches each and every feature of claim 28. The combination of the Rhodes '874 publication, the Kusano publication, and the Jung '472 publication discloses the features of claim 34, which depends from claim 28. As such, claim 34 is unpatentable under 35 U.S.C. § 103(a).

> Claim 34. The glucose sensor system of claim 28, further comprising an analog-to-digital converter configured to translate the current flow measurement to a digital signal.

While the Rhodes '874 publication does not explicitly state that the sensor electronics use an analog-to-digital converter, the Jung '472 publication shows how an analog-to-digital converter can be used in a glucose sensor to translate the current flow measurement to a digital signal. See, for example, the Jung '472 publication, [0034]-[0035]. One of skill in the art would understand that in order to convert the current flow from an analog signal to a digital signal, an analog-to-digital converter is necessary. In accordance with the teachings of the Jung '472 publication, one of skill in the art would recognize how to use an analog-to-digital converter in the sensor electronics of the Rhodes '874 publication. The sensor of claim 34 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 34 would have been obvious to one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication, the Kusano publication, and the Jung '472 publication. Claim 34 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

F. Claims 10, 26, and 40 are obvious under 35 U.S.C. § 103 in view of the Rhodes '874 publication, the Kusano publication, and the Sternberg publication.

Claims 10, 26, and 40 are unpatentable under 35 U.S.C. § 103(a) over the Rhodes '874 publication in view of the Kusano publication, and further in view of the Sternberg publication. Sections VI.F.1 – VI.F.3 detail how claims 10, 26, and 40 are rendered obvious by the teachings of the Rhodes '874 publication, the Kusano publication, and the Sternberg publication. For the examiner's convenience, the arguments presented below are summarized in the table provided in **Exhibit N**.

1. Dependent Claim 10

As outlined above, the combination of the Rhodes '874 publication and the Kusano publication teaches each and every feature of claim 1. The combination of the Rhodes '874 publication, the Kusano publication, and the Sternberg publication discloses the features of claim 10, which depends from claim 1. As such, claim 10 is unpatentable under 35 U.S.C. § 103(a).

> Claim 10. The glucose sensor system of claim 1, wherein the system is configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation

The Rhodes '874 publication describes the sensor as being used *in vivo* for over one year. The Rhodes '874 publication teaches the use of an immobilized glucose oxidase (GOx) as the enzyme. See, for example, the Rhodes '874 publication, [0004] and [0127]. The Sternberg publication describes three procedures for preparing electrodes with GOx (i.e., the enzyme employed in the sensor of the Rhodes '874 publication). See, for example, the Sternberg publication, pgs. 2782-83, and Table I. Procedures "a," "b," and "c" contain 3.0 ± 1.2 μg, 6.4 ± 2.2 μg, and 10 ± 1.4 μg of GOx, respectively. *Id.* More specifically, procedure "a" provides 3.8 ± 1.5 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 3.0 ± 1.2 μg of enzyme; procedure "b" provides 8.0 ± 2.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 6.4 ± 2.2 μg of enzyme; and procedure "c" provides 13 ± 1.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 10 ± 1.4 μg of enzyme.

As discussed on page 2784 of the Sternberg publication, "Figure 5 compares the time-dependent loss of enzymatic activity with the loss of enzyme mass from the membrane surface." The line noted with the "X" markers in Figure 5 (reproduced below) illustrates the consumption of GOx over about 15 days of continuous use.

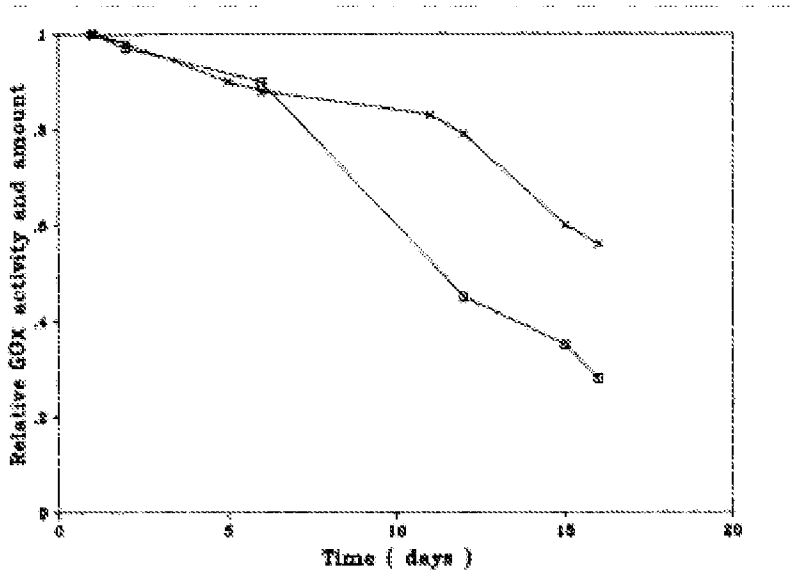


Figure 5. Relative evolution of surface GOx activity (O) and ^{125}I–GOx (X) in a CA–BSA–PBQ–GOx membrane not treated with lysine after coupling.

As shown in Figure 5, the relative consumption of GOx over the first seven days of use is between about 10% and about 15%. Enzyme prepared in accordance with procedure "a" would begin with 3.0 ± 1.2 μg, and result in a consumption of about 0.18-0.63 μg. Enzyme prepared in accordance with procedure "b" would begin with 6.4 ± 2.2 μg, and result in consumption of about 0.42-1.3 μg. Enzyme prepared in accordance with procedure "c" would begin with 10 ± 1.4 μg, and result in consumption of about 0.86-1.7 μg. As such, the Sternberg publication teaches how to configure the system to consume a range of enzyme mass from about 0.18-1.7 μg over 7 days of continuous operation.

One of skill in the art, in view of the teachings of the Sternberg publication, would thus appreciate how to configure the sensor "such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation." In other words, the Sternberg publication teaches three preparation procedures that can be used to prepare the GOx used in the Rhodes '874 publication in order to meet the claimed consumption limitation. The sensor of claim 10 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 10 would have been obvious to one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication, the Kusano publication, and the Sternberg publication. Claim 10 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

2. Dependent Claim 26

As outlined above, the combination of the Rhodes '874 publication and the Kusano publication teaches each and every feature of claim 12. The combination of the Rhodes '874 publication, the Kusano publication, and the Sternberg publication discloses the features of claim 26, which depends from claim 12. As such, claim 26 is unpatentable under 35 U.S.C. § 103(a).

> Claim 26. The glucose sensor system of claim 12, wherein the system is configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation.

The Rhodes '874 publication describes the sensor as being used *in vivo* for over one year. The Rhodes '874 publication teaches the use of an immobilized glucose oxidase (GOx) as the enzyme. See, for example, the Rhodes '874 publication, [0004] and [0127]. The Sternberg publication describes three procedures for preparing electrodes with GOx (i.e., the enzyme employed in the sensor of the Rhodes '874 publication). See, for example, the Sternberg publication, pgs. 2782-83, and Table I. Procedures "a," "b," and "c" contain 3.0 ± 1.2 μg, 6.4 ± 2.2 μg, and 10 ± 1.4 μg of GOx, respectively. *Id.* More specifically, procedure "a" provides 3.8 ± 1.5 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 3.0 ± 1.2 μg of enzyme; procedure "b" provides 8.0 ± 2.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 6.4 ± 2.2 μg of enzyme; and procedure "c" provides 13 ± 1.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 10 ± 1.4 μg of enzyme.

As discussed on page 2784 of the Sternberg publication, "Figure 5 compares the time-dependent loss of enzymatic activity with the loss of enzyme mass from the membrane surface." The line noted with the "X" markers in Figure 5 (reproduced below) illustrates the consumption of GOx over about 15 days of continuous use.

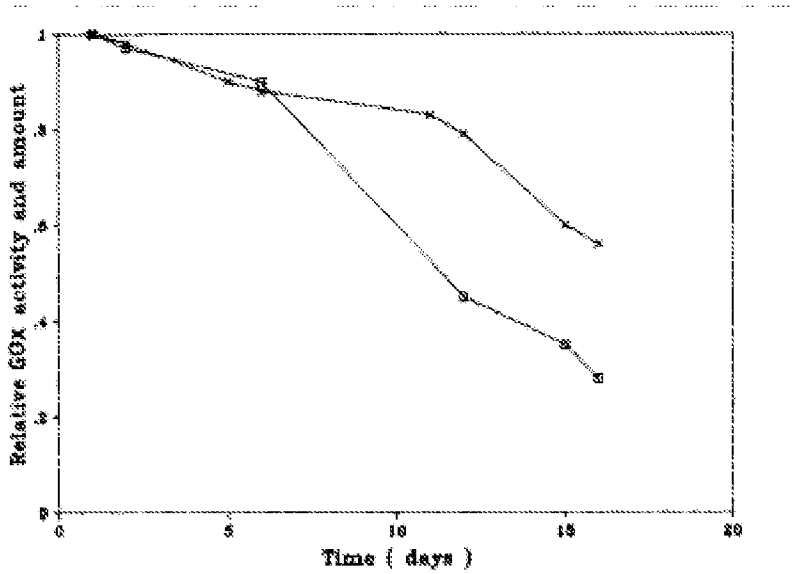


Figure 5. Relative evolution of surface GOx activity (O) and ^{125}I–GOx (X) in a CA–BSA–PBQ–GOx membrane not treated with lysine after coupling.

As shown in Figure 5, the relative consumption of GOx over the first seven days of use is between about 10% and about 15%. Enzyme prepared in accordance with procedure "a" would begin with 3.0 ± 1.2 μg, and result in a consumption of about 0.18-0.63 μg. Enzyme prepared in accordance with procedure "b" would begin with 6.4 ± 2.2 μg, and result in consumption of about 0.42-1.3 μg. Enzyme prepared in accordance with procedure "c" would begin with 10 ± 1.4 μg, and result in consumption of about 0.86-1.7 μg. As such, the Sternberg publication teaches how to configure the system to consume a range of enzyme mass from about 0.18-1.7 μg over 7 days of continuous operation.

One of skill in the art, in view of the teachings of the Sternberg publication, would thus appreciate how to configure the sensor "such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation." In other words, the Sternberg publication teaches three preparation procedures that can be used to prepare the GOx used in the Rhodes '874 publication in order to meet the claimed consumption limitation. The sensor of claim 26 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 26 would have been obvious to one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication, the Kusano publication, and the Sternberg publication. Claim 26 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

3. Dependent Claim 40

As outlined above, the combination of the Rhodes '874 publication and the Kusano publication teaches each and every feature of claim 28. The combination of the Rhodes '874 publication, the Kusano publication, and the Sternberg publication discloses the features of claim 40, which depends from claim 28. As such, claim 40 is unpatentable under 35 U.S.C. § 103(a).

> Claim 40. The glucose sensor system of claim 28, wherein the system is configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation.

The Rhodes '874 publication describes the sensor as being used *in vivo* for over one year. The Rhodes '874 publication teaches the use of an immobilized glucose oxidase (GOx) as the enzyme. See, for example, the Rhodes '874 publication, [0004] and [0127]. The Sternberg publication describes three procedures for preparing electrodes with GOx (i.e., the enzyme employed in the sensor of the Rhodes '874 publication). See, for example, the Sternberg publication, pgs. 2782-83, and Table I. Procedures "a," "b," and "c" contain 3.0 ± 1.2 μg, 6.4 ± 2.2 μg, and 10 ± 1.4 μg of GOx, respectively. *Id.* More specifically, procedure "a" provides 3.8 ± 1.5 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 3.0 ± 1.2 μg of enzyme; procedure "b" provides 8.0 ± 2.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 6.4 ± 2.2 μg of enzyme; and procedure "c" provides 13 ± 1.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 10 ± 1.4 μg of enzyme.

As discussed on page 2784 of the Sternberg publication, "Figure 5 compares the time-dependent loss of enzymatic activity with the loss of enzyme mass from the membrane surface." The line noted with the "X" markers in Figure 5 (reproduced below) illustrates the consumption of GOx over about 15 days of continuous use.

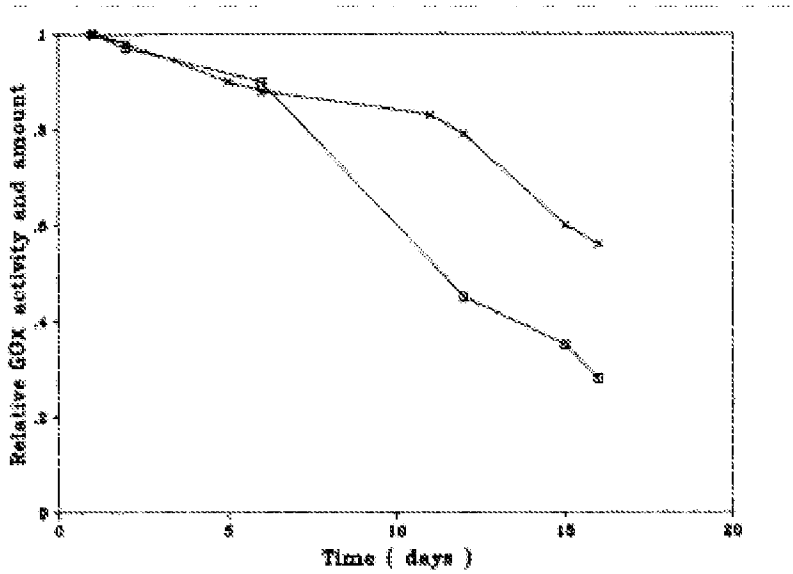


Figure 5. Relative evolution of surface GOx activity (O) and ^{125}I–GOx (X) in a CA–BSA–PBQ–GOx membrane not treated with lysine after coupling.

As shown in Figure 5, the relative consumption of GOx over the first seven days of use is between about 10% and about 15%. Enzyme prepared in accordance with procedure "a" would begin with 3.0 ± 1.2 μg, and result in a consumption of about 0.18-0.63 μg. Enzyme prepared in accordance with procedure "b" would begin with 6.4 ± 2.2 μg, and result in consumption of about 0.42-1.3 μg. Enzyme prepared in accordance with procedure "c" would begin with 10 ± 1.4 μg, and result in consumption of about 0.86-1.7 μg. As such, the Sternberg publication teaches how to configure the system to consume a range of enzyme mass from about 0.18-1.7 μg over 7 days of continuous operation.

One of skill in the art, in view of the teachings of the Sternberg publication, would thus appreciate how to configure the sensor "such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation." In other words, the Sternberg publication teaches three preparation procedures that can be used to prepare the GOx used in the Rhodes '874 publication in order to meet the claimed consumption limitation. The sensor of claim 40 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 40 would have been obvious to one of skill in the art; particularly in light of the teachings of the Rhodes '874 publication, the Kusano publication, and the Sternberg publication. Claim 40 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

G. Claims 28-33, 37, and 41 are obvious under 35 U.S.C. § 103 in view of the Kerner publication and the Kusano publication.

Claims 28-33, 37, and 41 are unpatentable under 35 U.S.C. § 103(a) over the Kerner publication in view of the Kusano publication. Sections VI.G.1 – VI.G.8 detail how claims 28-33, 37, and 41 are rendered obvious by the teachings of the Kerner publication and the Kusano publication. For the examiner's convenience, the arguments presented below are summarized in the table provided in **Exhibit O**.

1. Independent Claim 28

> Claim 28. A glucose sensor system comprising:
>
> *Part of Claim 28*

The Kerner publication teaches a glucose sensor system. See, for example, the Kerner publication, Summary, pg. 9, and FIG. 1.

The Kusano publication teaches a glucose sensor system. See, for example, the Kusano publication, Abstract, and FIGs. 3, 4, and 9.

> an electrode configured to measure a concentration of glucose in a host;
>
> *Part of Claim 28*

The Kerner publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See the Kerner publication, Summary, pg. 9, and FIG. 1.

The Kusano publication teaches an implantable body comprising an electrode configured to measure a glucose level in a host. See, for example, the Kusano publication pgs. 2-3, and FIG.

> a membrane disposed over the electrode and configured to limit transport of glucose to the electrode; and
>
> *Part of Claim 28*

The Kerner publication teaches a membrane disposed over the electrode, wherein the membrane includes a resistance domain configured to limit transport of glucose to the electrode and an enzyme to catalyze a reaction of glucose and oxygen. See the Kerner publication, Summary, pg. 9, and FIG. 1.

The Kusano publication teaches a polyurethane membrane disposed over the electrode. See, for example, FIG. 2. The membrane includes a resistance domain configured to limit transport of glucose to the electrode. See, for example, the Kusano publication, pgs. 1-3.

> sensor electronics operably connected to the electrode and configured to measure a current flow associated with the electrode;
>
> wherein the system is configured to have a glucose sensitivity of from about 1 pA/mg/dL to about 100 pA/mg/dL, and wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.3 mg/L.
>
> *Part of Claim 28*

The Kerner publication teaches sensor electronics operably connected to the electrode. The Kerner publication teaches the sensor system is configured to have, in operation, a sensitivity of from about 4.1 to 4.9 nA at 100 mg/dL (i.e., 41 to 49 pA/mg/dL), which falls within the claimed range of 1 pA/mg/dL to about 100 pA/mg/dL. See the Kerner publication, FIG. 4, and pg. 11. The electronics unit of the Kerner publication is configured to measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL. See the Kerner publication, Summary, FIGs. 4 and 5, and pg. 11. The system of the Kerner publication, however, measures glucose in a fluid with an oxygen concentration of above 0.5 mg/L. *Id.*

The Kusano publication teaches sensor electronics operably connected to the electrode. The sensor electronics measure a current produced by the electrode with substantial linearity at glucose concentrations of up to about 400 mg/dL, in a fluid with an oxygen concentration of less than about 0.3 mg/L. Specifically, the Kusano publication states, "The glucose electrode with percutaneous interface described in this paper differs from [previously described electrodes] using a novel approach to overcome the lack of oxygen in the interstitial fluid." *Id.* The Kusano publication further states:

> The electrode has a linear response to glucose concentration at an electrode output current ranging from 0 to 20nA ***even when the oxygen concentration of the glucose solution is zero***. The use of polyurethane as a diffusion barrier to glucose limits the electrode output current at a glucose concentration of 500 mg dl^{-1} (27.8 mmol l^{-1}) to 20 nA. Therefore, the electrode can measure glucose concentrations up to 500 mg dl^{-1} (27.8 mmol l^{-1}) ***with no oxygen*** dissolved in the glucose solution.

The Kusano publication, Abstract (emphasis added).

Figure 8 of the Kusano publication (reproduced below) shows a linear current measurement up to 500 mg/dL, even at 0 kPa of Po_2.

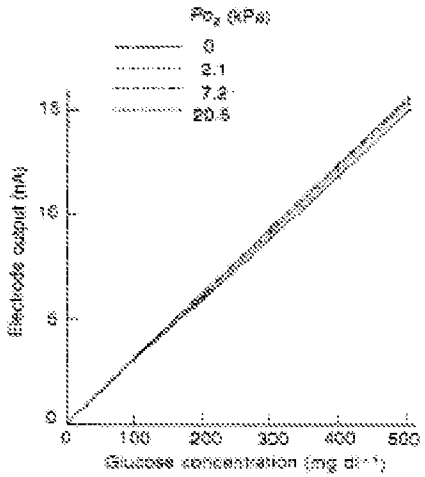


Figure 8. Electrode calibration curves under various Po_2

The concluding remarks of the Kusano publication further state:

> Glucose concentrations of 0 to 500 mg dl^{-1} (27.8 mmol l^{-1}) could be measured without being affected by oxygen concentration in the range of 0 to 163 mmHg (21.7 kPa). Since the electrode is capable of operating where the oxygen concentration is low, it is thought to be suitable for implantation in subcutaneous tissue and may prove to be a key development in the realisation of a closed-loop artificial endocrine pancreas.

The Kusano publication, pg. 8.

The Kusano publication states, "In addition, the steady state current at a glucose concentration of 500 mg/dL (27.8 mmol/L) should be less than the saturation current which results when the oxygen supplied from the air is limited, which is about 20 nA in this electrode." The Kusano publication, pg. 6. As such, the Kusano publication teaches a sensitivity of less than 40 pA/mg/dL (i.e., 20,000 pA divided by 500 mg/dL).

The sensor system of the Kusano publication employs an air intake hole to draw ambient air into the sensor, and thus configures the system to measure current flow associated with the electrode, with substantial linearity, at glucose concentrations of about 400 mg/dL, even in a fluid with an oxygen concentration at 0 mg/L. See, the Kusano publication, MATERIALS section, pgs. 2-3, and FIGs. 2 and 8. The air intake hole described in the Kusano publication is a

simple mechanical modification to a sensor, which provides ambient oxygen to the electroactive surface. One of ordinary skill in the art would understand how to modify the sensor of the Kerner publication to include the air intake hole of the Kusano publication, without undue experimentation and with reasonable expectation of success. Such modification does not change the chemistry, or general function of the sensor. Instead, such modification merely provides ambient oxygen to the sensor when the oxygen concentration within the fluid is inadequate for the function of the sensor. As such, the sensor of the Kerner publication can be combined with the air intake hole of the Kusano publication to measure glucose in a fluid with an oxygen concentration below 0.3 mg/L, as called for in claim 28. The sensor of claim 28 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 28 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication and the Kusano publication. Claim 28 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

2. Dependent Claim 29

In addition to showing each and every feature of claim 28, the combination of the Kerner publication and the Kusano publication discloses the features of claim 29, which depends from claim 28, and thus renders claim 29 obvious under 35 U.S.C. § 103(a).

> Claim 29. The glucose sensor system of claim 28, wherein the electrode comprises an exposed electroactive surface with an area of from about 0.000084 cm^2 to about 0.016 cm^2.

The Kerner publication teaches the electrode includes an exposed electroactive working electrode surface with a surface area between about 0.000084 cm^2 to about 0.016 cm^2. See the Kerner publication, pg. 9. More specifically, with a diameter of the working electrode at 0.5 mm, the surface area is equal to 0.00196 cm^2 (Area = πr^2 = (3.14)(0.25mm)^2 = 0.196 mm^2 = 0.00196 cm^2). *Id.*

The Kusano publication teaches an electroactive surface area that falls within the range of 0.000084 cm^2 to about 0.016 cm^2. Specifically, the Kusano publication teaches a working electrode with "0.5 μg of albumin-linked glucose oxidase [] immobilised at the tip" of a "Pt wire 0.5 mm in diameter." See the Kusano publication, Abstract. The surface area of the electroactive surface is therefore the surface area of the tip of the Pt wire, which is equal to

0.00196 cm^2 (Area = πr^2 = (3.14)(0.25mm)^2 = 0.196 mm^2 = 0.00196 cm^2). A surface area of 0.00196 cm^2 falls within the claimed range of about 0.000084 cm^2 to about 0.016 cm^2.

3. Dependent Claim 30

In addition to showing each and every feature of claim 28, the combination of the Kerner publication and the Kusano publication discloses the features of claim 30, which depends from claim 28, and thus renders claim 30 obvious under 35 U.S.C. § 103(a).

> Claim 30. The glucose sensor system of claim 28, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.15 mg/L.

As discussed above, the Kusano publication teaches a sensor configured to measure glucose concentrations "even when the oxygen concentration of the glucose solution is zero." The Kusano publication, Abstract. As such, the Kusano publication meets the claim limitation of the oxygen concentration being less than about 0.15 mg/L. More specifically, the sensor system of the Kusano publication employs an air intake hole to draw ambient air into the sensor, and thus configures the system to measure current flow associated with the electrode, with substantial linearity, at glucose concentrations of about 400 mg/dL, even in a fluid with an oxygen concentration at 0 mg/L. See, the Kusano publication, MATERIALS section, pgs. 2-3, and FIGs. 2 and 8. One of ordinary skill in the art would understand how to modify the sensor of the Kerner publication to include the air intake hole of the Kusano publication, and thus cure any oxygen deficiency by drawing in ambient oxygen to the sensor. Such modification would allow for the sensor of the Kerner publication to measure glucose in a fluid with an oxygen concentration below 0.15 mg/L, as called for in claim 30. The sensor of claim 30 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 30 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication and the Kusano publication. Claim 30 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

4. Dependent Claim 31

In addition to showing each and every feature of claim 28, the combination of the Kerner publication and the Kusano publication discloses the features of claim 31, which depends from claim 28, and thus renders claim 31 obvious under 35 U.S.C. § 103(a).

> Claim 31. The glucose sensor system of claim 28, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.05 mg/L.

As discussed above, the Kusano publication teaches a sensor configured to measure glucose concentrations "even when the oxygen concentration of the glucose solution is zero." The Kusano publication, Abstract. As such, the Kusano publication meets the claim limitation of the oxygen concentration being less than about 0.05 mg/L. More specifically, the sensor system of the Kusano publication employs an air intake hole to draw ambient air into the sensor, and thus configures the system to measure current flow associated with the electrode, with substantial linearity, at glucose concentrations of about 400 mg/dL, even in a fluid with an oxygen concentration at 0 mg/L. See, the Kusano publication, MATERIALS section, pgs. 2-3, and FIGs. 2 and 8. One of ordinary skill in the art would understand how to modify the sensor of the Kerner publication to include the air intake hole of the Kusano publication, and thus cure any oxygen deficiency by drawing in ambient oxygen to the sensor. Such modification would allow for the sensor of the Kerner publication to measure glucose in a fluid with an oxygen concentration below 0.05 mg/L, as called for in claim 31. The sensor of claim 31 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 31 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication and the Kusano publication. Claim 31 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

5. Dependent Claim 32

In addition to showing each and every feature of claim 28, the combination of the Kerner publication and the Kusano publication discloses the features of claim 32, which depends from claim 28, and thus renders claim 32 obvious under 35 U.S.C. § 103(a).

> Claim 32. The glucose sensor system of claim 28, wherein the system is configured to accurately measure glucose concentrations of up to about 400 mg/dL in a fluid with an oxygen concentration of less than about 0.02 mg/L.

As discussed above, the Kusano publication teaches a sensor configured to measure glucose concentrations "even when the oxygen concentration of the glucose solution is zero." The Kusano publication, Abstract. As such, the Kusano publication meets the claim limitation of

the oxygen concentration being less than about 0.02 mg/L. More specifically, the sensor system of the Kusano publication employs an air intake hole to draw ambient air into the sensor, and thus configures the system to measure current flow associated with the electrode, with substantial linearity, at glucose concentrations of about 400 mg/dL, even in a fluid with an oxygen concentration at 0 mg/L. See, the Kusano publication, MATERIALS section, pgs. 2-3, and FIGs. 2 and 8. One of ordinary skill in the art would understand how to modify the sensor of the Kerner publication to include the air intake hole of the Kusano publication, and thus cure any oxygen deficiency by drawing in ambient oxygen to the sensor. Such modification would allow for the sensor of the Kerner publication to measure glucose in a fluid with an oxygen concentration below 0.02 mg/L, as called for in claim 32. The sensor of claim 32 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 32 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication and the Kusano publication. Claim 12 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

6. Dependent Claim 33

In addition to showing each and every feature of claim 28, the combination of the Kerner publication and the Kusano publication discloses the features of claim 33, which depends from claim 28, and thus renders claim 33 obvious under 35 U.S.C. § 103(a).

> Claim 33. The glucose sensor system of claim 28, wherein the sensor electronics are configured to directly measure the current flow associated with the electrode.

The Kerner publication teaches sensor electronics configured to directly measure the current flow associated with the electrode. See the Kerner publication, Summary, pg. 9, and FIG. 1.

7. Dependent Claim 37

In addition to showing each and every feature of claim 28, the combination of the Kerner publication and the Kusano publication discloses the features of claim 37, which depends from claim 28, and thus renders claim 37 obvious under 35 U.S.C. § 103(a).

> Claim 37. The glucose sensor system of claim 28, wherein the membrane comprises an enzyme.

The Kerner publication teaches a membrane disposed over the electrode, wherein the membrane includes a resistance domain configured to limit transport of glucose to the electrode and an enzyme to catalyze a reaction of glucose and oxygen. See the Kerner publication, Summary, pg. 9, and FIG. 1.

The sensor of the Kusano publication includes an enzyme configured to catalyze a reaction of glucose and oxygen. See, for example, the Kusano publication, pgs. 1-3, and FIG 2.

8. Dependent Claim 41

In addition to showing each and every feature of claim 28, the combination of the Kerner publication and the Kusano publication discloses the features of claim 41, which depends from claim 28, and thus renders claim 41 obvious under 35 U.S.C. § 103(a).

> Claim 41. The glucose sensor system of claim 28, wherein the membrane comprises a polyurethane.

The Kusano publication teaches the membrane comprising a polyurethane. See the Kusano publication, pg. 6.

H. Claim 34 is obvious under 35 U.S.C. § 103 in view of the Kerner publication, the Kusano publication, and the Jung '472 publication.

Claim 34 is unpatentable under 35 U.S.C. § 103(a) over the Kerner publication in view of the Kusano publication, and further in view of the Jung '472 publication. Provided below is an explanation as to how claim 34 is rendered obvious by the teachings of the Kerner publication, the Kusano publication, and the Jung '472 publication. For the examiner's convenience, the arguments presented below are summarized in the table provided in **Exhibit P**.

As outlined above, the combination of the Kerner publication and the Kusano publication teaches each and every feature of claim 28. The combination of the Kerner publication, the Kusano publication, and the Jung '472 publication discloses the features of claim 34, which depends from claim 28. As such, claim 34 is unpatentable under 35 U.S.C. § 103(a).

> Claim 34. The glucose sensor system of claim 28, further comprising an analog-to-digital converter configured to translate the current flow measurement to a digital signal.

While the Kerner publication does not explicitly state that the sensor electronics use an analog-to-digital converter, the Jung '472 publication shows how an analog-to-digital converter can be used in a glucose sensor to translate the current flow measurement to a digital signal. See, for example, the Jung '472 publication, [0034]-[0035]. One of skill in the art would understand that in order to convert the current flow from an analog signal to a digital signal, an analog-to-digital converter is necessary. In accordance with the teachings of the Jung '472 publication, one of skill in the art would recognize how to use an analog-to-digital converter in the sensor electronics of the Kerner publication. The sensor of claim 34 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 34 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication, the Kusano publication, and the Jung '472 publication. Claim 34 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

I. Claim 40 is obvious under 35 U.S.C. § 103 in view of the Kerner publication, the Kusano publication, and the Sternberg publication.

Claim 40 is unpatentable under 35 U.S.C. § 103(a) over the Kerner publication in view of the Kusano publication, and further in view of the Sternberg publication. Provided below is an explanation as to how claim 40 is rendered obvious by the teachings of the Kerner publication, the Kusano publication, and the Sternberg publication. For the examiner's convenience, the arguments presented below are summarized in the table provided in **Exhibit Q**.

As outlined above, the combination of the Kerner publication and the Kusano publication teaches each and every feature of claim 28. The combination of the Kerner publication, the Kusano publication, and the Sternberg publication discloses the features of claim 40, which depends from claim 28. As such, claim 40 is unpatentable under 35 U.S.C. § 103(a).

Claim 40. The glucose sensor system of claim 28, wherein the system is configured such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation.

The Sternberg publication describes three procedures for preparing electrodes with immobilized glucose oxidase (GOx). See, for example, the Sternberg publication, pgs. 2782-83, and Table I. Procedures "a," "b," and "c" contain 3.0 ± 1.2 μg, 6.4 ± 2.2 μg, and 10 ± 1.4 μg of GOx, respectively. *Id.* More specifically, procedure "a" provides 3.8 ± 1.5 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 3.0 ± 1.2 μg of enzyme; procedure "b" provides 8.0 ± 2.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 6.4 ± 2.2 μg of enzyme; and procedure "c" provides 13 ± 1.8 μg/cm^2 on a membrane surface of 0.8 cm^2, which equates to 10 ± 1.4 μg of enzyme.

As discussed on page 2784 of the Sternberg publication, "Figure 5 compares the time-dependent loss of enzymatic activity with the loss of enzyme mass from the membrane surface." The line noted with the "X" markers in Figure 5 (reproduced below) illustrates the consumption of GOx over about 15 days of continuous use.

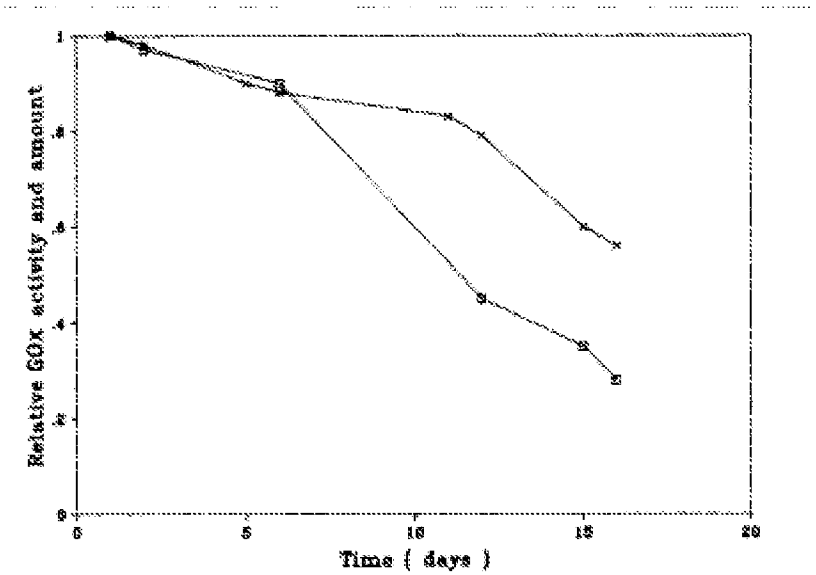


Figure 5. Relative evolution of surface GOx activity (O) and ^{125}I–GOx (X) in a CA–BSA–PBQ–GOx membrane not treated with lysine after coupling.

As shown in Figure 5, the relative consumption of GOx over the first seven days of use is between about 10% and about 15%. Enzyme prepared in accordance with procedure "a" would begin with 3.0 ± 1.2 μg, and result in a consumption of about 0.18-0.63 μg. Enzyme prepared in

accordance with procedure "b" would begin with 6.4 ± 2.2 μg, and result in consumption of about 0.42-1.3 μg. Enzyme prepared in accordance with procedure "c" would begin with 10 ± 1.4 μg, and result in consumption of about 0.86-1.7 μg. As such, the Sternberg publication teaches how to configure the system to consume a range of enzyme mass from about 0.18-1.7 μg over 7 days of continuous operation.

One of skill in the art, in view of the teachings of the Sternberg publication, would thus appreciate how to configure the sensor "such that less than about 1 μg of enzyme is consumed over 7 days of continuous operation." The sensor of claim 40 offers no more than the predictable use of prior art elements according to their established functions. As such, claim 40 would have been obvious to one of skill in the art; particularly in light of the teachings of the Kerner publication, the Kusano publication, and the Sternberg publication. Claim 40 is therefore unpatentable under 35 U.S.C. § 103(a). *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007).

VII. CERTIFICATION OF SERVICE (37 C.F.R. § 1.510(b)(5))

The United States Patent and Trademark Office records indicate that the Shults '511 patent is presently assigned to DexCom, Inc. (see Assignment recorded at Reel/Frame: 017588/0674). The undersigned certifies that the request for *ex parte* reexamination has been served by Federal Express, deposited on March 31, 2011, on the patent owner at the correspondence address provided in the USPTO PAIR system:

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VIII. STATEMENT OF AUTHORITY TO ACT ON BEHALF OF THE REAL PARTY IN INTEREST PURSUANT TO 37 C.F.R. § 1.34

The undersigned states that he is acting on behalf of the Requestor, Abbott Diabetes Care Inc., in a representative capacity pursuant to 37 C.F.R. § 1.34.

IX. CONCLUSION

For the reasons given above, reexamination of claims 1-41 of U.S. Patent No. 7,899,511 is respectfully requested.

The USPTO is directed and authorized to charge all Requestor's required fees associated with the Request to Deposit Account No. 50-0815, order number ADCI-GEN55, as well as credit any overpayments to said Deposit Account.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

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XI. EXHIBIT LIST

Exhibit No.	Description
Exhibit A	U.S. Patent No. 7,899,511 to Shults *et al.*, issued on March 1, 2011.
Exhibit B	U.S. Patent Application Publication No. 2003/0032874 to Rhodes *et al.*, published on February 13, 2003.
Exhibit C	Kusano, H., Glucose enzyme electrode with percutaneous interface which operates independently of dissolved oxygen, *Clin. Phys. Physiol. Meas.*, vol. 10, 1:1-9 (1989).
Exhibit D	Kerner, *et al.*, A Potentially Implantable Enzyme Electrode for Amperometric Measurement of Glucose, *Horm Metab Res Suppl.*, 20:8-13 (1989).
Exhibit E	U.S. Patent Application Publication No. 2004/0173472 to Jung *et al.*, filed September 28, 2001.
Exhibit F	Sternberg, *et al.*, Covalent Enzyme Coupling on Cellulose Acetate Membranes for Glucose Sensor Development, *Anal. Chem.*, 60: 2781-2786 (1988).
Exhibit G	A complete listing of the claims for which reexamination is requested.
Exhibit H	Table summarizing the renumbering of the application claims.
Exhibit I	Table illustrating that each element of claims 1, 2, 4-9, 11-18, 21, 23-25, 27-30, 33, 35-39, and 41 is provided by the Rhodes '874 publication.
Exhibit J	Table illustrating that each element of claims 3, 22, and 34is provided by the Rhodes '874 publication and the Jung '472 publication.
Exhibit K	Table illustrating that each element of claims 10, 26, and 40 is provided by the Rhodes '874 publication and the Sternberg publication.
Exhibit L	Table illustrating that each element of claims 1, 2, 4-9, 11-21, 23-25, 27-33, 35-39, and 41 is provided by the Rhodes '874 publication and the Kusano publication.
Exhibit M	Table illustrating that each element of claims 3, 22, and 34 is provided by the Rhodes '874 publication, the Kusano publication, and the Jung '472 publication.
Exhibit N	Table illustrating that each element of claims 10, 26, and 40 is provided by the Rhodes '874 publication, the Kusano publication, and the Sternberg publication.
Exhibit O	Table illustrating that each element of claims 28-33, 37, and 41 is provided by the Kerner publication and the Kusano publication.

Exhibit P	**Table illustrating that each element of claim 31 is provided by the Kerner publication, the Kusano publication, the Jung '472 publication.**
Exhibit Q	**Table illustrating that each element of claim 40 is provided by the Kerner publication, the Kusano publication, the Sternberg publication.**